OFFICE OF THE CENTER DIRECTOR

Review of Human Subject Research

CONTENTS

PURPOSE

- This MAPP establishes the policies and procedures employees must follow in the Center for Drug Evaluation and Research (CDER) when submitting human subject research for review to FDA's Institutional Review Board (IRB), the Research Involving Human Subjects Committee (RIHSC).

BACKGROUND

- FDA has provided assurance to the Department of Health and Human Services (DHHS) that all activities related to human subject research will (1) be guided by the ethical principles outlined in the Belmont Report (see References), (2) comply with the Office for Human Research Protection's (OHRP) terms of assurance for protection of human subjects, and (3) comply with DHHS regulations for the protection of human research subjects, including provisions of the Federal Policy for the Protection of Human Subjects (45 CFR part 46 subpart A). As part of this assurance, FDA has established policy that, except for those categories of research specifically exempted or waived under the DHHS regulations and not otherwise included by FDA policy, all human subject research conducted, supported, or funded in whole or in part by FDA will be reviewed and approved by an institutional review board (IRB) established by FDA. The RIHSC is FDA's established IRB.

REFERENCES

- 45 CFR part 46 (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm)
- "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," the National Commission for the Protection of Human Subjects of Biomedical and Behavioral

Research, Office of the Secretary, DHHS, April 18, 1979 (the Belmont Report) (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm)

- "Federalwide Assurance of Protection for Human Subjects," OHRP, DHHS (http://ohrp.osophs.dhhs.gov/humansubjects/assurance/filasurt.htm)
- "FDA Internal Operating Procedures for the Research Involving Human Subjects Committee" (http://first.fda.gov/Rihsc/document/RIHSCwrittenproceduresfinal.doc)
- Draft "FDA Policy on the Review and Clearance of Articles to be Published in Scientific or Professional Journals" (http://intranet.nctr.fda.gov/planning/documents/FDAPublicationPolicy.pdf)

DEFINITIONS

- **Research in Human Subjects Committee (RIHSC)**: FDA's institutional review board (IRB), located in the Office of Science and Health Coordination, FDA.

- **RIHSC liaison**: The CDER staff member designated by the Center Director to review any human subject research in which CDER employees participate, or plan to participate, for possible review by the RIHSC.

- **Human subject**: "A living individual about whom an investigator . . . conducting research obtains (1) data through intervention or interaction with an individual, or (2) identifiable private information." (45 CFR 46.102(f))

- **Research**: "A systematic investigation, including research, development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." (45 CFR 46.102(d))

- **Human subject research**: Includes, but is not limited to:
  - All FDA intramural projects
  - All off-site studies, domestic or foreign, including studies with other government agencies
  - All focus group testing or survey research
  - All retrospective research involving record reviews
  - All research using human biological materials
  - All studies using FDA's private database information, either alone or in collaboration with another government agency
  - All studies that have IRB approval from other organizations, including approval from other government entities

- **FDA Internal Standard Operating Procedures for the Research Involving Human Subjects Committee (FDA's SOPs)**: The standard operating procedures that apply to all human subject research conducted, supported, or funded in whole or in part by FDA.

POLICY

- Any CDER employee who is, or plans to be, involved in human subject research must submit the research for review to CDER's RIHSC liaison (CDER's liaison). CDER's liaison will assess whether the submitted materials on the research are sufficient to allow a review by the CDER liaison and the RIHSC. When sufficient information has been submitted, the CDER liaison will make a recommendation to the RIHSC regarding the extent of the review needed — exemption, expedited review, or full RIHSC review.

- All CDER employees involved in human subject research must complete training in the relevant human subject protection rules and regulations and must receive certification of completion.

RESPONSIBILITIES

CDER Employees

- All CDER employees who currently are, or plan to be, involved in human subject research must submit materials detailing the research to CDER's liaison, as outlined in FDA's SOPs. All materials should be sent to CDER's liaison through the Office of Executive Programs (OEP).

- All CDER employees must submit contracts, task orders, work orders, requests for proposals, and any other documents involving human subject research to CDER's liaison prior to their announcement of availability. All materials should be sent through OEP.

- All CDER employees planning focus group testing or survey research that requires clearance through the Office of Management and Budget (OMB) must submit documents to CDER's liaison prior to submission to OMB.

- CDER employees do not need to send grant applications for human subject research to the CDER liaison until they are funded. The actual human subject portion of the grant cannot begin without review by CDER's liaison and the RIHSC.

- CDER employees must comply with any provisions for continuing review required by the RIHSC.

- All CDER employees using federal funds for human subject research must have completed training in the DHHS regulations on human subject protection and must have obtained a certification of completion. CDER employees may contact CDER's OEP for training materials to complete this requirement. Continuing education credits for physicians are available on completion of this training.

- All CDER employees involved in human subject research must read and be familiar with FDA's SOPs and the Belmont Report.

- All CDER employees who seek to publish the results of human subject research must adhere to the policies found in FDA's SOPs, including any FDA policy applicable to clearance of articles for publication.

CDER Liaison

- The CDER liaison will review all materials on ongoing or future human subject research in a timely manner to make a Center recommendation to the RIHSC on the actions required by the RIHSC for the research proposed — exemption, expedited review, or full RIHSC review. The CDER liaison will consider scientific merit, ethical concerns, program relevance, and public responsibility. Upon making the Center determination, the CDER liaison, or a representative, will also report the recommendation to the CDER employee.

- The CDER liaison will determine for the Center whether the research is exempt from RIHSC review and submit that recommendation to the RIHSC to receive a Letter of Exemption.

- If the research is not eligible for exemption, the CDER liaison will determine for the Center the level of review needed by the RIHSC (expedited or full) and submit that recommendation to the RIHSC.

- When the CDER liaison determines that the research needs RIHSC review, the CDER liaison will provide oversight to employees in completing the necessary forms and will forward those forms to the RIHSC.

Office of Executive Programs

- OEP will maintain records of all human subject research reviewed by the CDER liaison and RIHSC, including protocols, letters of exemption, and all relevant documents sent to and received from the RIHSC for a minimum of 3 years after completion of the research.

- OEP will maintain documentation that CDER employees involved in human subject research have received training in human subject protection rules and regulations.

- Upon request, OEP will provide information to any CDER employee on how to receive necessary training in the regulations related to human subject research and a certification of completion.
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- OEP maintains a repository of information of all research activities in the Center and the costs related to those activities. This may include the training of individuals on entering data into a centralized database.

PROCEDURES

- CDER employees should submit to OEP the materials outlined in FDA's SOPs detailing any human subject research for review by the CDER liaison.

- The CDER liaison, or a representative, will contact the employee, as necessary, to discuss any questions, obtain more information, or establish any further procedures necessary to

make determinations and ensure CDER's compliance with FDA's SOPs and policies on human subject research.

- CDER employees should contact OEP for information on how to receive a certification of completion for necessary training in human subject regulations.

AUTHORITY

- 45 CFR part 46
- U.S. Department of Health and Human Services Federal-wide Assurance (FWA) for the Protection of Human Subjects for Domestic (U.S.) Institutions

EFFECTIVE DATE

This MAPP is effective upon date of publication.