

# Cleveland Clinical and Translational Science Collaborative: Human Research Protection Program

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## INTRODUCTION

Case Western Reserve University (CASE) and its affiliated hospitals comprise one of the largest human subject research centers in the country. An important component of the Cleveland Clinical and Translational Science Collaborative (CTSC) is the Case Human Research Protection Program (HRPP), which covers the review of elements of human subject research conducted by any student, employee, faculty member of Case, University Hospitals (UH), the Cleveland Clinic (CC) and The MetroHealth System (MHS). The integration of the associated human research review programs allows for enhanced oversight of human subject research between the four financially separate institutions since resources are shared, including IRB review, education of researchers and compliance monitoring.

The purpose of this poster is to provide the historical context about the collaboration between the four institutions and to discuss the ways in which the collaboration will grow and evolve as part of the Cleveland CTSC initiative. The collaboration between Case and its affiliated hospitals signifies the context in which the Cleveland CTSC creates a collaborative environment aimed at the essential activities required for a safe, efficient and successful HRPP for research subjects and investigators.

## BACKGROUND

The Case, UH and MHS human subject research collaboration began in the early 1970's prior to Department of Health and Human Services (DHHS) assurance requirements. Case faculty members, as human subject researchers, act as a common thread among the organizations. Essentially, all principal investigators are Case faculty members and are also employees of one or more of the affiliated medical centers at the same time. The physician investigators will also have admitting privileges at one or more of the affiliated medical centers. Case, as the academic institution, does not own any of the affiliated medical centers, but has one of the leading medical schools in the country. As a result, affiliations with the above medical centers have been critical for physician training, the conduct of human subject research and appropriate IRB review.

As the advent of DHHS assurance requirements in the 1980's, Case, UH and MHS entered into a Multiple Project Assurance (MPA) Agreement whereby Case would rely upon IRBs housed at the medical centers to review human subjects research conducted at each site. For example, a faculty member who performed a National Institute of Health (NIH) funded clinical trial at UH and MHS would be required to show IRB approval from each institution to Case in order to have access to their grant funding. Each medical center was responsible for reviewing industry sponsored clinical research where the medical centers themselves act as the grantees.

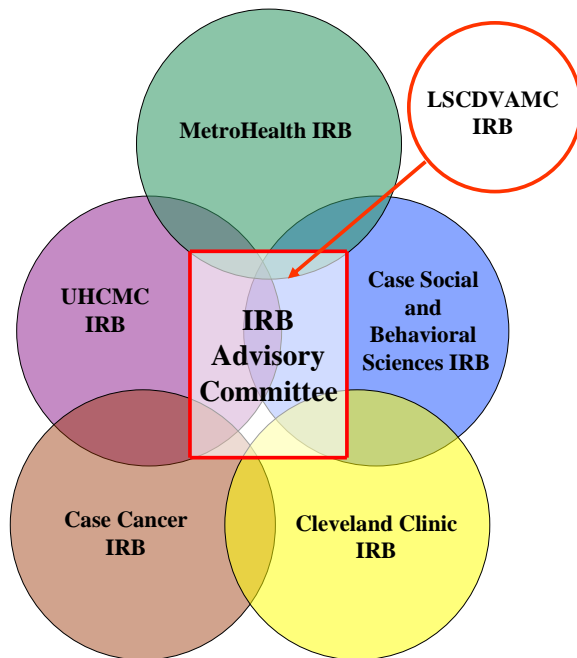
Throughout this time Case also maintained its own IRB, which was responsible for reviewing social science and behavioral research, as well as research emanating from the Schools of Nursing and Dentistry. At that time, the collaboration among the institutions for the protection of human subjects was generally limited to negotiating the assurance.

As the assurance programs at academic medical centers across the country began to fall under increased scrutiny in the mid to late 1990s, Case and its affiliates began formal work, with the assistance of the Office for Protection from Research Risks (OPRR), to develop a more detailed collaborative program designed to continue to ensure that all institutional regulations and obligations were met through standard approaches aimed at human subject protections among the affiliated institutions. A year prior to the expiration of the then existing MPA, Case, UH, MHS and Louis Stokes Cleveland Department of Veteran's Affairs Medical Center provided a detailed description of an oversight program that not only set standards across the institutions for human subject protections, but also dealt with oversight responsibilities related to the financial relationships between the institutions, while addressing the large amount of diverse research conducted at each of the institutions.

## IRB ADVISORY COMMITTEE

In order to create such a collaborative program, an advisory group was formed with representatives from each institution. Discussions among the institutions resulted in the creation of the IRB Advisory Committee (IAC) (Figure 1). The IAC was composed of two voting members from each member institution (Case, UH, MHS and LSCDVAMC), was chaired by the Case Associate Vice President for Research (Organizational Official), and administered by each of the participating institutions through the Case Office of Research Compliance. It enabled each party to better oversee the entire HRPP system through semi-annual reporting and quality assurance auditing requirements. As part of its mission to share resources, address current research/regulatory challenges and promote collaboration among member institutions, the IAC holds regular training sessions for its members. The IAC is responsible for determining the content of such training with the assistance of the Case Office of Research Compliance, which is responsible for organization and implementation.

Figure 1: Pictorial Representation of the Case HRPP



Subsequently, Case entered into a formal collaboration agreement with CC in 2003 to act as the NIH grantee for research conducted at CC, which included shared oversight responsibilities for related human subject protocols. As a result, CC joined the IAC as a voting member.

A prominent example of the collaboration among these organizations with the support of the IAC resulted in the creation of the Case Cancer IRB in 2005. The Case Cancer IRB formally brings together the Ireland Cancer Center of UH and the Taussig Cancer Center of CC under one Case Comprehensive Cancer Center with respect to the review and approval of all cancer and cancer-related research. This is accomplished through FWA IRB authorization agreements between UH and Case and CC and Case, that allow for the Case Cancer IRB to be the IRB of record for cancer and cancer-related protocols conducted at the medical centers.

## MISSION

The collaborative mission of the Case HRPP is to protect the rights, dignity, welfare, and privacy of humans who participate in research programs governed by the participating institutions while providing efficient administrative processes for investigators. The Case HRPP adheres to the Principals of the Belmont Report and the federal, state and local laws that govern human subject research. As part of the Cleveland CTSC, the Case HRPP will advance the responsible conduct of research by formalizing best practice human research review by:

- Providing centralized oversight of the HRPP and establishing local IRB standard
- Sharing resources and best practices among Cleveland CTSC institutions and other institutions
- Creating dynamic and collegial environment of respect and understanding of the rights and welfare of human research subjects
- Educating research community on federal regulations and ethical principles guiding research with humans
- Providing researchers with current up to date information on regulations and ethical principles in their particular area of research
- Continue to review and implement new approaches that better serve the HRPP mission, such as IRB office operations, review of the research, protocol tracking, benchmarking and monitoring research activities
- Providing a framework to perform quality assurance auditing of clinical research

## IAC ACCOMPLISHMENTS

- NIH Grant for IRB Infrastructure
- Creation of research in local context review programs for international research
- Providing standard educational sessions for all IRB Chairs, IRB members and IRB staff within the collaborative organizations
- Accreditation through the Association of the Accreditation of Human Research Protection Programs (AAHRPP) for 3 of the 5 IRBs within the Case HRPP
- Creation of Cancer IRB model within Case NCCP

## GOALS

During the first year, the primary goal of the Case HRPP under the Cleveland CTSC has evolved into increased attention toward further streamlining of processes for CTSC investigators submitting clinical research protocols at each of the collaborating institutions. Suggestions for achieving further efficiencies of the Case HRPP include the following:

- Complete reciprocity of IRB review (i.e. increased reliance on each other's IRBs to achieve greater efficiencies)
- Decisions about the lead site will be based primarily on the principal investigator's main affiliation and will be formalized through the CTSC concierge service mechanism
- Development of standardized submission guidelines for all institutions
- Coordination of various electronic IRB review systems

## CHALLENGES

Challenges that need to be overcome to achieve an even more fully integrated and collaborative HRPP are as follows:

- Achieve and maintain full accreditation of each individual IRB under the Case HRPP
- Recognize the need for institutional "local context" or institutional specific requirements for the review of clinical research protocols
- Overcoming the challenges presented by differences in physical locations across the city of Cleveland by better utilizing technology