Ⅳ　バイバンクによる創薬研究

「NDRI and HAB Partnership to Serve Science and Advance Research」

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The National Disease Research Interchange (NDRI) was founded in 1980 in Philadelphia, Pennsylvania, U.S.A., as a not-for-profit organization with a mission to procure and distribute human biospecimens to researchers to advance research. NDRI has been supported, in part, by the National Institute of Health (NIH) for more than 30 years. In 1996 the Human Animal and Bridge Research Organization (HAB) of Japan formed a partnership with NDRI. The objective of this partnership is to create a path by which Japanese researchers in academic and pharmaceutical industry settings can legally procure and use human biospecimens.

NDRI has provided HAB in excess of 12,000 human biospecimens to date for distribution to researchers over the course of this partnership. A few examples biospecimens provided and their experimental use include:

- Skin: This tissue is extremely beneficial for drug toxicity and drug metabolism studies, and through a wide variety of tissue, basic research and drug development studies that can be further developed.
- Cartilage: Objectives of research utilizing cartilage are to verify that technical and theoretical advantages of scaffold techniques have superior histological, biochemical and physical characteristics as compared with conventional methods.
- Ocular: Objectives of research projects utilizing ocular tissue include identification of the disease related molecules in ocular tissue to develop targeted drugs for Age-related macular degeneration (AMD) and Diabetic retinopathy (DR).

How NDRI Works

On a daily basis, NDRI interacts with scientists in academic, corporate and independent research institutions from around the world. In the preliminary stages of establishing a new biospecimen request from a researcher, NDRI collaborates directly with scientists to define their precise human biospecimen needs for their respective research projects. The request is then finalized via NDRI's vetting and application process and a research project is created. NDRI staff manage and coordinate each biospecimen request and recovery directly with NDRI's network of U.S. tissue source sites. To accommodate a broad spectrum of requests, this network is comprised of a diverse range of partners: organ procurement organizations, eye and tissue banks, hospitals, pathology departments and academic research institutions. All biospecimens procured for distribution by NDRI are from highly regulated U.S. based tissue source sites.

The tissue source sites and NDRI collectively evaluate potential donation opportunities relative to the pre-established research project criteria. Donation opportunities are shared with NDRI Fulfillment Coordinators who staff a call center which operates 24 hours a day, seven days a week and 365 days a year. If a donation offer coincides with a researcher's request, the source site identifies the highest class of next-of-kin, as defined by the Uniform Anatomical Gift Act (UAGA). Next, the tissue source site obtains consent and provides NDRI with written documentation of authorization and the donor medical history summary forms. NDRI requires compliance with the UAGA.

After careful review of the consent documentation, an NDRI Fulfillment Coordinator approves the suitable organs/tissues for recovery. The tissue source site begins the recovery process immediately following acceptance by NDRI. The organs/tissues are to be prepared for shipment by the remote collection center in accordance with the instructions provided by NDRI. The instructions are specific to biospecimen recovery, packaging and shipment methods for each pre-approved project. NDRI assigns a unique identifier (donor number) to each recovered donor. This donor number is the only identifying information provided to a researcher. Upon receipt of tissue, the researcher, or designee, must complete a customer survey to confirm the safe arrival of their biospecimen(s) from NDRI.

NDRI provides both normal and diseased specimens to between four-hundred and five-hundred scientists annually. NDRI serves researchers domestically and internationally. Scientists supported by NDRI are engaged in a wide spectrum of research areas including neuroscience, endocrinology, hematology, immunology, ophthalmology, gastroenterology, oncology and many other areas. The most frequently requested diseased tissues include cancer, rare diseases, diabetes, musculoskeletal, HIV, neurological and ocular.

Future Directions

The genetic diversity at the single cell and subcellular levels are one of the next scientific frontiers for human biospecimen analysis. Cell-specific differences in transcriptome, proteome, and metabolome profiles within human tissues or organs are proving to be major hindrances for basic research and translational medicine. However, recent advances in scientific experimental methodologies and biospecimen procurement practices have ameliorated several key issues that have enabled investigators to expand beyond tissue-level analysis. Investigators now can perform cutting-edge experimental procedures on individual cells in human tissues and organs.

These recent advances are driving the newly emerging research trend to develop large-scale research projects that will unveil the molecular diversity of every individual cell type in the human body. Collectively, single-cell projects will provide the research community and the public with several open-access atlases that catalog the molecular identities of every single cell from all human tissues, organs and body systems.

Advancing into the field of single-cell analysis is a natural next step for NDRI. The benefits of single-cell projects will be at least 2-fold: (1) determine the molecular signature of each distinct cell type in each human tissue and organ, and (2) provide more accurate data by removing the problematic effects of “averaged results” from tissue-level analysis that contains mixed population cells. These two key points are major limitations for all prior scientific studies using human tissues and organs.

NDRI is pleased to be embarking on a range of single-cell projects with prestigious U.S.-based research institutions. NDRI is committed to responding to the changing needs of the biomedical research community to facilitate breakthroughs in human biology and physiology. Conquering cell-specific differences in human tissues and organs will move findings at the bench another step closer to the bedside; these landmark scientific discoveries will yield better treatments and cures for patients.

NDRI は 1980 年フィラデルフィアに、ヒト試料を科学の発展のため供給することを使命として設立された非営利団体である。1996 年以来 HAB と連携し、わが国の多くの研究者にヒト試料を提供してきた。

NDRI は臓器調達機関、アイバンク、組織バンク、医療機関、病理部門、学術研究施設などとネットワークを構築し、統一死体提供法に基づいて 365 日 24 時間、コーディネーターが研究者の多様な要求に応じその役割を果たしている。国内外の数百に及ぶ多くの医療分野の研究者に正常および病的組織を供給している。

今後の方向性として、これまでの組織・臓器レベルの検討から、一つ一つの細胞に特異的なトランスクリプトーム、プロテオーム、メタボロームなどの解析に進んでゆくものと考えられる。それは最先端の方法を駆使して、生体を構成する一つ一つの細胞における分子レベルでの多様性と特異性を明らかにするプロジェクト（The Single Cell Analysis Program, SCAP）である。世界の研究機関が共同でその成果を、包括的かつ体系的な Human Cell Atlas を作成し、疾患の診断、病態の解明さらには治療に役立てようとする試みである。性別、年齢、遺伝的要素などの多様性の解析から、トランスクリプト、プロテオミクス、メタボロミクスなど、分子レベルでの個々の細胞の特異性の解明を目指す、真の意味での precise medicine の幕開けとも言えよう。

これはかつての全ゲノム解明のプロジェクトにも匹敵すべき壮大なプロジェクトであり、その意味では NDRI およびそれに連携する HAB によるヒト試料の提供の役割は今後ますます重要なものとなると考えられる。