Public Summary
Investigational Drug Steering Committee
Friday, January 15th (2010)

1. **Call to Order, Announcements, and Review of Minutes**
    a. **Presentation of plaque**: Charles Erlichman received a plaque for his two-years of service as the IDSC N01 co-chair from James Doroshow.
    b. **New IDSC N01 co-chair:** Dan Sullivan (Moffitt) began his two-year term as IDSC N01 co-chair on January 1, 2010.
    c. **CTEP update:** James Zwiebel gave an update on CTEP solicitations (**see Attachment 1**) and discussed the OEWG kick-off meeting for U01, N01 and Cooperative Group representatives on Tuesday, March 23rd.
2. **Introduction to the Clinical Proteomics Technologies for Cancer (CPTC):** Kim Jessup provided a brief overview of the CPTC to IDSC members. Mehdi Mesri (from CPTC) will give a full presentation on this topic to IDSC members at the March 23rd-24th meeting.
    a. CPTC and its programs now seek to collaborate with IDSC, SPORES, and Cancer Centers in areas of mutual interest.
    b. Can assist with multiplex assays for measuring analytes that are modified by agent or pathway activity.
    c. Welcomes opportunities to identify and develop assays and reagents for preclinical and early phase trials.
3. **IDSC Strategic Initiatives for CY2010:** IDSC co-chairs (Michael Grever and Dan Sullivan) presented and discussed prioritization of the Task Force/Working Group strategic initiatives for CY2010.
    a. **See Attachment 2** for full strategic initiative listing
    b. **Upcoming publications:** PAM subgroup 3 (hyperglycemia/hyperlipidemia) and Biomarker TF pre-analytical variables
    c. **Upcoming educational sessions or workshops:**
        i. DNA Repair TF: Autophagy educational session at CTEP EDD (March 23rd)
        ii. DNA Repair TF: PARP Workshop (March 22nd)
        iii. Biomarker TF CTEP EDD educational session (March 22nd)
        iv. Suggestions for September 2010 CTEP EDD: Disease progression modeling session was suggested by Mark Ratain and Merrill Egorin.
4. **Brief Update on CTEP Drug Development Plans – c-Met**
    a. The MK-8033 CTEP solicitation has been placed on-hold.
    b. ARQ-197 and SCH900105 may proceed as planned with CTEP (*further information is confidential*).
5. **IP Option Update:** Sherry Ansher and Jason Cristofaro presented the updates to the CTEP IP Option to IDSC members.
    a. The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis (DCTD) obtains "Agents" from biotechnology and pharmaceutical companies (hereinafter "Collaborators") for use in NCI-funded research via collaborative research agreements. As part of its arrangement with these Collaborators, DCTD must ask the extramural community receiving the Agent to agree to certain conditions. **See Attachment 3** for full details.

6. **Revised CTEP AE Guidelines:** Percy Ivy presented upcoming changes to the AE guidelines in 2009-2010.
    a. **Upcoming Changes in 2009-2010?**
        i. An expedited AE reporting scale was developed for trials conducted under a CTEP-held IND to more closely tailor the reporting needs for a study based on:
            1. Extent of clinical experience with the agent (s).
            2. Need to maintain patient safety and regulatory compliance
            3. IDB/CTEP collective medical experience
        ii. There will now be 4 expedited reporting levels assigned by CTEP staff following these general guidelines:
            1. Level A: Phase 0 trials (only level reporting Grade 1 AEs)
            2. Level B: Phase 1 and early Phase 2 trials
            3. Level C: Late Phase 2 and Phase 3 trials
            4. Level D: Phase 2 and Phase 3 trials with Commercially-available agents
7. **OEWG Update:** James Doroshow presented the Operational Efficiency Working Group (OEWG) Report regarding Phase 2 and 3 trials that are NCI-sponsored. Membership included 63 clinical trial stakeholders.
    a. **Please see link for complete slide set:** http://deainfo.nci.nih.gov/ADVISORY/ctac/1109/presentations/OEWG_Doroshow.pdf
    b. **Operational Efficiency Working Group Background:**
        i. Clinical Trials Working Group (CTWG) Report Operational Efficiency Initiative 2
            1. Identify the institutional barriers that prolong the time from concept approval to accrual of first patient, and develop solutions for overcoming these barriers.
        ii. Clinical Trials Advisory Committee (CTAC) Charge
            1. Establish an Operational Efficiency Working Group (OEWG) to recommend strategies and implementation plans for reducing the time for activation of Cooperative Group and Cancer Center trials.
        iii. Focus is on timeliness of trial activation
            1. Trial quality being addressed by several other CTWG and CTAC initiatives.
    c. **OEWG Deliberations:**
        i. Agreement on key barriers to timely trial activation
        ii. Commitment to achieve new target timelines for steps in trial activation
        iii. Developed new process maps for trial activation
        iv. Identified external factors outside of NCI or investigators' control that delay activation
        v. Developed recommendations and associated implementation plans to achieve target timelines
        vi. Established firm dates to terminate protocol development if all issues are not resolved.
    d. There were 11 Recommendations that came out of this Working Group to date, please see complete slide set (link above) for further details.
8. **Clinical Trial Design TF Update (**Percy Ivy**):**

a. Phase I workshop and recommendations: Focus Series in Clinical Cancer Research – March 2010
b. Phase II recommendations: Focus Series in Clinical Cancer Research March 2010
c. Phase II simulation comparing adaptive design and frequentist approach (Groshen/Berry)
d. Phase II historical controls database (Crowley, LeBlanc & Rubinstein)
e. Discussion of phase 2/3 data repository proposal (*further information is confidential*)
f. Phase II Recommendations: Metrics for recent CTEP LOIs (*further information is confidential*)

9. **LOI Review WG Recommendations:** Dan Sullivan (WG co-chair) presented the preliminary recommendations/suggestions from the LOI Review WG to IDSC members.
    a. **Approved Motion by IDSC:** The IDSC shall form a LOI Working Group to assess and form recommendations to improve the efficiency of LOIs from phase I U01 and phase II N01 grantees/contractors.
    b. Suggestions involving fostering of collaboration and incentivization between U01 and N01 holders were presented (to increase accrual per site and scientific excellence).
    c. *Various other ideas were expressed by IDSC members at the meeting, which are confidential*.
10. **Immunotherapy TF Update:** Mario Sznol provided a brief update of the Immunotherapy TF activities.
    a. Added new members: Jedd Wolchok, Robert Vonderheide, Madhav Dhodapkar, Marc Theoret, and Patrick Hwu.
    b. Committee priorities for CY2010:
        i. Assist CTEP in obtaining key agents
        ii. Assist with CTEP Drug Development Plans
        iii. Position paper – Adoptive immunotherapy opportunities and strategies for advancing development
        iv. Clinical endpoints for immunotherapy trials (CTEP EDD session)
        v. Address need/issues for antigens/vaccines in CTEP portfolio
11. **PI3K/Akt/mTOR (PAM) Task Force:** Afshin Dowlati presented the update hyperglycemia/hyperlipidemia recommendations to IDSC members. PAM subgroup 3 will continue development of a manuscript.
12. **Metrics Working Group:** The Career Development LOI (CRDL) Survey was presented by Anthony Murgo (WG co-chair) to IDSC members. This survey was developed to assist NCI Cancer Therapy Evaluation Program (CTEP) Investigational Drug Branch (IDB) staff evaluate the Career Development LOI (CRDL) process.
13. **DNA Repair and Programmed Cell Death (RAD) Task Force:**
    a. Autophagy session will be held at the CTEP Spring EDD meeting on March 23rd 2010.
    b. Face to face TF meeting on PARP inhibitors will be held during the Spring 2010 CTEP/IDSC meeting on Monday, March 22nd in the evening. Disease-specific Steering Committees will be invited to nominate two representatives to this meeting.
14. **IDSC Disease-specific Steering Committee (SC) Liaisons:**
    a. Lillian Siu will become the new IDSC Head and Neck SC liaison.
    b. Michael Grever will become the new IDSC Leukemia SC liaison.
    c. Dan Sullivan will become the new IDSC Myeloma SC liaison.
    d. Joe Sparano will be approached about becoming the new IDSC Lymphoma SC liaison.

15. Biomarker Task Force

a. **Biomarker educational session - Spring 2010 Early Drug Development (EDD) meeting: Topic**: Issues in Development of Companion Diagnostics for Novel Therapeutics
b. The Biomarker Task Force recommendations manuscript was accepted by Clinical Cancer Research (CCR) and will be published in the March 2010.
c. Biomarker strategic initiatives for CY2010 were discussed (**see Attachment 2 for listing**)

16. Future Calls/Meetings/Plans

a. EDD/IDSC Spring 2010 meeting: Monday-Wednesday, March 22-24 2010 (Bethesda, MD)
b. OEWG Kick-off meeting: Tuesday, March 23rd in evening (Bethesda, MD)
c. EDD/IDSC Fall 2010 meeting: Monday-Wednesday, September 27-29 2010 (Bethesda)

ATTACHMENT 1

Agent Name	Inhibits	IDSC Review	Mass Solicitation Status?
IMC-A12	IGF-1R	September 2006	Issued
IL-12	immune regulation	July 2008	Issued
SCH727965	cdk	February 2008	Issued
GDC-0449	sonic hedgehog	November 2008	Issued
RO4929097	notch	January 2009	Issued
OSI-906	IGF-1R	March 2009	Pending
MK-2206	akt	March 2009	Issued
ABT-263	bcl2, BH3 mimetic	April 2009	Issued
AZD8055	mTOR	May 2009	ON-HOLD
ARQ-197	cMet	October 2009	Pending
SCH900105	cMet	October 2009	Pending
MK-8033	cMet	October 2009	ON-HOLD
AT13387	HSP90	Ocotber 2009	ON-HOLD

ATTACHMENT 2

2009 Strategic Initiative Statistics:

- 70 percent of initiatives were completed
- 20 percent of initiatives are still ongoing
- 10 percent were never started

Accomplishments in 2009:

- IDSC reviewed nine CTEP agents in 2009 (RO4929097, MK-2206, OSI-906, ABT-263, AZD8055, AT13387, MK-8033, ARQ-197, and SCH900105)
- Manuscripts published or in review in 2009
  - Phase I CCR Focus articles (Clinical Trial Design TF; to be published March 2010)
  - Phase II CCR Focus articles (Clinical Trial Design TF; published in March 2009)
  - Biomarker TF recommendations in CCR (part of Phase I CCR Focus articles; to be published in March 2010)
  - Hypertension manuscript from the Cardiovascular Toxicities Panel to be published in JNCI (Angiogenesis TF)
- IDSC annual survey for 2009
- Educational Sessions at CTEP Early Drug Development (EDD) Meeting in 2009:
  - Wnt educational session (Cancer Stem Cell TF)
  - Phase II recommendations (Clinical Trial Design TF)
  - Biomarker TF recommendations (Biomarker TF)
  - JAK-STAT educational session (Signal Transduction)
  - c-Met educational session (Signal Transduction)

Highlighted Strategic Initiatives in 2009:

- Clinical Trial Design Phase II recommendations (approved July 2009)
- Phase I CCR Focus articles (to be published March 2010) by the Clinical Trial Design and Biomarker TF
- Phase 2/3 database proposal by Clinical Trial Design TF
- Educational sessions discussed above at CTEP Early Drug Development (EDD) Meeting (Wnt, JAK-STAT, c-Met, etc.)
- Biomarker TF: CLIA Workshop at Spring 2009 IDSC meeting
- Biomarker TF: Review biomarker aspects of CTEP development plans for specific agents as requested by the IDSC.
- Angiogenesis TF: HTN manuscript to be published in JNCI; second manuscript from Cardiovascular Toxicities Panel (CTP) should be completed soon.
- Cancer Stem cell: Reviewed RO4929097 and GDC-0449 for CTEP.
- PAM (PI3K/Akt/mTOR) subgroup 1 and gap analysis of mTOR inhibitors
- PAM subgroup 3 and recommendations for hyperglycemia/hyperlipidemia toxicities involving PAM agents

- Biomarker TF development and completion of a manuscript on biomarker recommendations for early clinical trials
- DNA Repair TF: Preformed a gap analysis for GX15-070, AT-101, and ABT-888
- Immunotherapy TF: Assisted with structure of Cancer Immunotherapy Network (CITN)
- Immunotherapy TF: Assisted with IL-12 CTEP Drug Development Plan
- Signal Transduction TF: Review current status of STAT3 and JAK2 inhibitors with invited experts
- Signal Transduction TF: Review Pim kinase inhibitors with invited experts
- Signal Transduction TF: Review proteosome inhibitors with invited experts
- Signal Transduction: Discuss geranylgeranyl transferase as a new targets
- Metrics WG: Submit recommendations to make IDSC processes more efficient and effective
- Metrics WG: Develop and implement survey to CTEP, DTP, DCP, and IDSC members for feedback
- Metrics WG: Create a list of publication principles that can be used to guide IDSC TFs on what to publish, how to go about it, and who to involve
- Pharmacology TF: Review pharmacological aspects of CTEP development plans for specific agents as requested by the IDSC.

Proposed Strategic Initiatives for CY2010 (by TF or WG):

Angiogenesis TF:

- Complete Cardiovascular Toxicities Panel manuscript on ventricular dysfunction and myocardial ischemia (project # 2)
- Distribution plan of the HTN manuscript (project # 1) to CTEP and other investigators; incorporation into CTEP protocols
- Prioritization of potential new agents/targets into CTEP
- Review new CTEP Drug Development Plans under Angiogenesis

Biomarker TF:

- Development of a plan to circulate the biomarker recommendations approved by the IDSC and manuscript to CTEP investigators
- Manuscript on pre-analytic and analytix variables on results of biomarker assays
- Development of an educational tool and process from perspective of tissue-based biomarker assays
- Development of a process for reference assays
- Workshop/Educational Session on Biomarkers
- Development of a mechanism to provide input to IDB involving LOI review and the use of biomarkers
- Assist DCTD/DTP in the prioritization of assay development
- Assist IDB-caHUB project

Cancer Stem Cell:

- Review of new CTEP Drug Development Plans under Cancer Stem Cell
- Prioritize new agents/targets for CTEP portfolio
- Consideration of DLL4 targeting agents
- Consideration of parthenolide targeting against AML stem cells
- Consideration of BMI-1 targeting agents
- Consider development of biomarkers for CSC targeting trials
- Educational sessions regarding CSC and the epithelial-mesenchymal transition

Clinical Trial Design:

- Adaptive/Frequentist Simulations
- Historical Controls
- Waterfall Plots
- Imaging Project
- Benchmarking: Phase 2 Designs
- Phase 2 design – solicitation
- Combination Studies Subcommittee

DNA Repair and Programmed Cell Death TF:

- Organize an autophagy educational program with CTEP on Programmed Cell Death with invited experts (a series of small calls will be set-up for discussion of speakers, agenda, etc.)
- Develop potential manuscript from the Autophagy EDD session or PARP Workshop
- Give input for a solicitation for agents involved in programmed cell death
- PARP Workshop
- Assist with review of CTEP Drug Development Plans under DNA Repair and Programmed Cell Death (RAD)
- Focus on additional agents/targets for CTEP portfolio (example: SMAC)

Immunotherapy TF:

- Assist CTEP in prioritization of vaccines/antigens for development
- Assistance in development of CTEP immunotherapy mass solicitations – subcommittees to be formed for IL-15 and anti-TGF-beta to tackle development plans
- Discussion of how to integrate immunotherapy with targeted therapy including novel endpoints
- CTEP EDD of evaluation for immunologic agents including the new proposed irRESIST
- General consensus (and SOPs) on collection of sera/plasma, lymphocytes, and tumor tissue at baseline, and post-treatment, in selected CTEP-sponsored immune therapy studies

- Critically assess the current Adoptive immunotherapy results and provide guidance to CTEP on how to direct resources towards this in the future (white paper to be developed and presented to IDSC)
- Discuss best uses for CITN once it is formed

Metrics WG:

- Make recommendations about how to use IDSC published guidelines to IDSC and to CTEP, e.g.
    - Implementation plan with external community
    - Use as evaluation criteria for RFPs, solicitations, etc.
- Assist TFs and WGs to create usable 'how to' procedures (e.g. flowcharts, decision trees, etc.), based on IDSC published guidelines.
- Development of the CRDL LOI survey
- Assist LOI Review WG with any process issues
- Follow up on 2009 Metrics WG recommendations to the IDSC-CT
- Creation of the CY2010 IDSC Survey

PAM TF:

- Review of CTEP Drug Development Plans with PAM agents (as needed)
- Subgroup 3: Completion of hyperglycemia/hyperlipidemia recommendations for PAM agents
- Subgroup 3: Completion of hyperglycemia/hyperlipidemia manuscript for PAM agents
- Subgroup 4: Novel targets and pathways to recommend to CTEP

Pharmacology TF:

- Review pharmacological aspects of CTEP development plans for specific agents as requested by the IDSC.

Signal Transduction TF:

- Ongoing review of new CTEP Drug Development Plans
- Refine cMet CTEP Drug Development Plans
- Discuss ALK as a drug target
- Review ALK inhibitors with invited experts
- Review/recommendation of HSP90 inhibitors
- Review/recommendation of Stat inhibitors (with JAK2 inhibitors or separately)
- Review/recommendation of proteasome inhibitors (inhibitors of the ubiquitin/proteasome system (immunoproteasome inhibitors, NEDD inhibitors, ubiquitin ligase inhibitors)
- Educational session on microenvironmental determinants of drug sensitivity of tumor cells
- Re-evaluation of Chk1/ATM inhibitors

- Review newer CDK inhibitors
- Review newer epigenetic agents e.g., HMT inhibitors, histone demethylase inhibitors
- Review newer Raf inhibitors +/- MEK1/2 inhibitors

Next steps:

- Need to prioritize 2010 initiatives within each TF.
- Coordinating Team needs to look across TF to make sure overlapping efforts are communicated.
- Get IDSC recommendations implemented w/training programs through AACR, ASCO, ASH, AAMC, etc.

ATTACHMENT 3

January 8, 2010

Intellectual Property Option (DRAFT)

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute's (NCI) Division of Cancer Treatment and Diagnosis (DCTD) obtains "Agents" from biotechnology and pharmaceutical companies (hereinafter "Collaborators") for use in NCI-funded research via collaborative research agreements. As part of its arrangement with these Collaborators, DCTD must ask the extramural community receiving the Agent to agree to certain conditions detailed below:

References to "Institution" shall mean the entity conducting the research described herein. The Intellectual Property Option (IP Option) described in the sections below will apply to inventions arising from research involving the Agent(s) under the scope of an NCI collaborative agreement.

A. The IP Option described in this Section A will apply to inventions which use or incorporate the Agent(s) and which were conceived or first actually reduced to practice pursuant to clinical or non-clinical studies utilizing the Agent(s) ("Section A Inventions"):

Institution agrees to grant to Collaborator(s): (i) a royalty-free, worldwide, non-exclusive license for commercial purposes; and (ii) a time-limited first option to negotiate an exclusive, or co-exclusive, if applicable, world-wide, royalty-bearing license for commercial purposes, including the right to grant sub-licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution. If Collaborator accepts the non-exclusive commercial license, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs which will be pro-rated and divided equally among all licensees. If Collaborator obtains an exclusive commercial license, in addition to any other agreed upon licensing arrangements such as royalties and due diligence requirements, the Collaborator agrees to pay all out of pocket patent prosecution and maintenance costs. Collaborator(s) shall notify Institution, in writing, if it is interested in obtaining a commercial license to any Section A Invention within three (3) months of Collaborator's receipt of a patent application or six (6) months of receipt of an invention report notification of such Section A Invention. In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Section A Invention, and Institution will be free to dispose of its interests in accordance with its policies. If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Section A Invention, then for a period of three (3) months thereafter Institution shall not offer to license the Section A Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept or reject the offer.

For all Section A Inventions, regardless of Collaborator's decision to seek a commercial license, Collaborator will be granted a paid-up, nonexclusive, royalty-free, world-wide license for research purposes only. Institution shall retain the right to make and use any Section A Invention for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so.

B. The IP Option described in this Section B will apply to inventions which do not use or incorporate the Agent(s) but which were conceived or first actually reduced to practice pursuant to clinical or non-clinical studies utilizing the Agent(s). It shall also apply to inventions which are conceived or first actually reduced to practice pursuant to studies utilizing clinical data or specimens from patients treated with the Agent (including specimens obtained from NCI-funded tissue banks) ("Section B Inventions"):

Institution agrees to grant to Collaborator(s): (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Section B Inventions for research purposes only; (ii) a time-limited first option to negotiate a non-exclusive, exclusive, or co-exclusive, if applicable, world-wide royalty-bearing license for commercial purposes, including the right to grant sub-licenses, subject to any rights of the Government of the United States of America, on terms to be negotiated in good faith by the Collaborator(s) and Institution and (iii) a nonexclusive, royalty-free, world-wide license to disclose and to promote Section B Inventions that are necessary or required by a regulatory authority for marketing authorization of the Agent or required to be on a product insert or other promotional material regarding the Agent or useful for informing Healthcare providers and patients regarding use of the Agent. Collaborator shall notify Institution, in writing, of its interest in obtaining e an exclusive commercial license to any Section B Invention within one year of Collaborator's receipt of a patent application or eighteen months of receipt of an invention report notifying Collaborator of such Section B Invention(s). In the event that Collaborator fails to so notify Institution, or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Section B Invention, and Institution will be free to dispose of its interests in such Section B Invention in accordance with Institution's policies. If Institution and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Institution may agree) on the terms for an exclusive license for a particular Subject B Invention, then for a period of six (6) months thereafter Institution shall not offer to license the Section B Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept or reject the offer. Institution shall retain the right to make and use any Section B Inventions for all non-profit research, including for educational purposes and to permit other educational and non-profit institutions to do so.

Inventions arising more than five years after completion of the clinical trial that generated the clinical data and/or specimens will not be subject to Section B (ii) IP Option..

A. Institution Notification

Institution agrees to promptly notify CTEP, NCI (NCICTEPpubs@mail.nih.gov) and Collaborator(s) in writing of any Section A Inventions or Section B Inventions upon the earlier of: (i) any submission of any invention disclosure to Institution of a Section A Invention or a Section B Invention, or (ii) the filing of any patent applications of a Section A Invention or a Section B Invention. Institution will provide a copy of either the employee invention report or the patent application to the Collaborator and to CTEP, NCI which will treat it confidentially. These requirements do not replace any reporting requirements under Bayh-Dole to the extent federal funding agreements are involved in this research. If Collaborator elects to negotiate an exclusive commercial license to a Section A or Section B Invention, then Institution agrees to file and prosecute patent application(s) diligently and in a timely manner and will give Collaborator an opportunity to comment on the preparation and filing of any such patent application(s). Notwithstanding the above, Institution is under no obligation to file or maintain patent prosecution for any Section A Invention or Section B Invention.

B. Unauthorized use of Collaborator material

Among those conditions under which NCI is making Collaborator Agent available to the extramural research community is the assurance that no unauthorized modifications to the Agent will be created and that no unauthorized research with the Agent will be conducted. If a receiving party conducts any unauthorized activities with the Agent, DCTD is obligated to report it to the Collaborator of the investigational Agent once DCTD becomes aware of it.

For inventions made by Institution's investigator(s) or any other employees or agents of Institution, which are or may be patentable or otherwise protectable, as a result of unauthorized research ("Unauthorized Inventions"), Institution will be required, at Collaborator's request and expense, to grant to Collaborator a royalty-free exclusive or co-exclusive license to the Unauthorized Invention.

Protection of Proprietary Data

Clinical data and results and raw data will be provided to the NCI, the Collaborator(s), and the FDA, as appropriate. Additionally, all clinical data and results and raw data will be collected, used and disclosed consistent with all applicable federal statutes and regulations for the protection of human subjects, including, if applicable, the *Standards for Privacy of Individually Identifiable Health Information* set forth in 45 C.F.R. Part 46. Notwithstanding the above, this provision shall not affect the investigator's right to use data research purposes, publish or present.