All Investigators who require assays to be run by the Core Lab should discuss their needs with the Core Lab at least 4 weeks prior to the scheduled RCAC review of the protocol or prior to the start of the study for non-CRC studies. This will allow time for the Core Lab to ensure that all necessary equipment, reagents, resources, and personnel time will be available to accommodate the request.

Samples
The RCMI Hormone Assay Core Lab is equipped to run assays on whole blood, plasma, serum, urine, other body fluids (e.g., CSF, saliva, washings, or other serous fluids), or media or cell extracts from in vitro experiments. In the case of plasma, serum, or other fluids that may contain cellular elements (e.g., saliva, washings, media or cell lysates), it is the responsibility of the Investigator/Study Coordinator to verify that these cellular elements will not interfere with the specificity or the interpretability of the assay results. Assays using samples of whole tissue (e.g., biopsies, sacrificed organs) must be discussed with the Core Lab to determine feasibility, as significant additional processing time and labor may be required. Investigators must also indicate the ideal storage conditions for all samples to be assayed, since the capacity of the Core Lab will be limited and assays must be performed in the appropriate sequence as determined by the Core Lab policies and the RCAC. Priorities will be assigned according to considerations such as time of receipt, study funding source, relative importance to the CRC goals, and batching or multiplexing arrangements to optimize labor and costs.

Methods
The RCMI Hormone Assay Core Lab is presently equipped to run assays using the following methodologies:
   - Radioimmunoassays (RIA)
   - Enzyme-linked immunosorbent assays (ELISA)
However, the Core Lab may discuss with PI’s the feasibility of conducting any assay using alternate techniques. In these cases, the project must be discussed with the Core Lab well in advance, to establish whether the Core Lab is capable of accessing the necessary equipment or expertise.

The Hormone Assay Core Lab will periodically re-examine and revise its techniques and procedures, as needed, in order to keep current with emerging technologies so as to remain competitive with other laboratories and currently accepted methodologies.

Analytes
The Hormone Assay Core Lab has experience in assaying the following analytes:
   - Total Testosterone, Free Testosterone
   - Dihydrotestosterone (DHT)
   - Androstenedione
   - Estradiol
   - Estrone
   - Luteinizing Hormone (LH)
   - Follicle Stimulating Hormone (FSH)
Sex Hormone Binding Globulin (SHBG)
Prostate-Specific Antigen (PSA)
Angiotensigen
Renin
Insulin
Leptin
Adiponectin
Ghrelin
Highly-sensitive C-reactive Protein (hsCRP)

The Core Lab is equipped to run assays on samples from any species (including Human, Mouse, Rat) provided that species-specific reagents for the specific analyte of interest are available. Such reagents may be obtained commercially or may be provided by the Investigator.

It is expected that the above list of analytes will grow, as the scope of the Core Lab’s experience expands with time. The Hormone Assay Core Lab is eager to expand its repertoire of analytes, particularly into other areas such as cardiovascular or tumor markers, and is willing to explore the development of these assays with prospective investigators as needed. For most analytes, it is expected that the establishment of these alternate assays should be feasible (provided that all other requirements to conduct the study at the CRC are met), but the details of the required assay(s) must be discussed with the Core Lab well in advance.

Assay Optimization
In developing assays for which the Core Lab has no previous direct experience, the following scheme outlines the Core Lab’s preferences and requirements in order to validate and implement the assay:

1. Assays using commercially available reagents should ideally be in kit form, providing most if not all required reagents and quality control data indicating the expected results for each analyte of interest.

2. If no commercial standardized kit is available, the Investigator must provide a referenced protocol indicating the assay procedure in detail, as well as the expected results, and then meet with the Core Lab to review the detailed protocol and to ensure that all of the reagents and equipment specified are accessible to the Core Lab. In such cases, additional time will be needed for test runs to ensure that the protocol yields the expected results in the hands of the Core Lab, and this may entail additional costs. Any reagents provided specifically by the Investigator (e.g., specialized antibodies) should be accompanied by the Investigator’s own quality control data that verifies the purity, specificity, and precision of the reagent.

3. Provided that the necessary equipment and reagents are accessible to the Core Lab personnel to conduct the assay, in the absence of a commercial standardized kit, if no existing protocol is available in detail from the literature for the Core Lab to use as a template, or no quality control data is available to validate the performance of the assay, it will be necessary for the Core Lab to conduct all of the required preliminary runs to establish parameters of quality control, such as the expected positive and negative control results, potential for false positive and false negative results, accuracy to a gold standard comparison test, reproducibility and precision, and susceptibility to assay-related factors such as declining reagent quality, unforeseen variations in assay conditions, and potential errors introduced by human manipulation. This will also entail additional delays and costs associated with the time, labor and reagents consumed in this
optimization process. Potential Investigators are strongly encouraged to perform ahead of time, or at least ensure (and provide documentation for) the quality control of the proposed assay, in order to facilitate the conduct of the assay for the Core Lab, as well as avoid any undue delays in obtaining data for their study.

4. Assays that require equipment and/or reagents that are not accessible to the Core Lab, or that require training and optimization that is beyond the immediate scope of the Core Lab’s capabilities (e.g., in situ hybridization, real-time RT-PCR), will not be performed. The Investigator may be referred to other labs with expertise and/or experience in these specialized assay techniques for assistance.

**Charges**

Any samples to be assayed by external commercial labs should be prepared, sent, and the results collected by the study’s Investigator/Study Coordinator who will also coordinate the relevant charges directly with the corresponding lab. The CRC also provides laboratory services through the KDMC clinical labs for common general chemistry and hematology assays on human blood and urine specimens, and payments for these services will be coordinated between the CRC and the Investigator. The Hormone Assay Core Lab will only conduct those assays not covered by the CRC’s arrangement with the KDMC clinical labs, and that are to be performed on-site.

For these assays, a system of charges to the Investigator’s study account will be established to cover the costs associated with performing the assays in the quantity requested. A list of the per-sample cost for each analyte under a given technique will be provided, and will be subject to revision from time to time to meet changing costs of Core lab operations. The costs will encompass the Core Lab’s direct per-sample expenses for the reagents and consumable supplies, regardless of the actual quantity requested (although bulk discounts may be established at the discretion of the Core Lab), as well as the per-sample portion of costs associated with technician time, requisite technical training and credentialing updates. The total cost will be billed directly to each Investigator’s account at an interval of time to be negotiated with each Investigator, depending on the overall volume of samples to be processed. Details of the chargeback system are outlined in the Administrative Procedures section, below.

**Assay Priorities**

Definitions:

*NIH-funded*: any project that is primarily funded by money from an NIH grant that is either specific to the project, for a parent NIH center grant that includes the project in question as a pilot/subproject, or from “soft money” maintained within existing Drew University funds (irrespective of the ultimate origins of such funds).

*Non-NIH-funded*: any project that is primarily funded by external (i.e., non-Drew) money from a source other than the NIH (e.g., industry, private foundations).

*CRC Study*: any project that has been accepted by the RCAC through its standard review process.

*Non-CRC Study*: any project that does not need the CRC facilities (e.g., *in vitro* studies, vivarium studies)

*Investigator-initiated*: any project that was originated by the PI, irrespective of the funding source, for which the Investigator stands to be first author on the future publication.

*Prominent authorship*: 1st, 2nd or 3rd author.
Depending on the funding source and the importance of the study to the function of the CRC, assays will be performed by the Core Lab according to the priorities outlined below. However, in special circumstances, Investigators may request that their samples receive a higher priority when required as preliminary results for the purposes of a pending grant submission. All of the following conditions must be met in order to honor an Investigator’s request to assume a higher priority than that outlined below:

a. The assay requested must be one that the Core Lab personnel have experience with, and are capable of performing with at most a minimum of laboratory reorganization. New assays or new laboratory techniques cannot be performed for this purpose.

b. The Investigator must currently have, or previously had, an RCAC-approved study that utilizes the Core Lab or the CRC. New Investigators who are unfamiliar with the operations of the Core Lab or the CRC cannot be accommodated as last minute, high-priority requests.

c. A reasonable time frame to complete the necessary assays, in the capacity required, must be provided prior to the scheduled deadline. Since the resources of the Core Lab personnel may be limited, the Core Lab has absolute discretion in making its individualized decision in each case as to whether the needs of the Investigator’s request can be met. While the Core Lab recognizes the importance of meeting grant deadlines, and will make every effort to meet the Investigator’s request, the Core Lab cannot guarantee that the results will be available in time if an unreasonably short time interval is provided.

Notwithstanding the above exception for pending grant submissions, the performance of assays by the Core Lab will be prioritized according to the following sequence:

1. NIH-funded, CRC studies at Drew: (e.g., NIH grant for a clinical trial awarded to a Drew PI)
All requested hormone assays for such studies must be made available. All samples must still be collected and processed by the Investigator/Study Coordinator, but the assay will be run by Core Lab personnel. Charges will be negotiated directly between the Core Lab and the study account.

2. Non-NIH-funded, investigator-initiated, CRC studies at Drew: (e.g., Industry/private grant for a clinical trial awarded to a Drew PI)
For all hormone assays that will not be run by central labs as determined by the Study’s Sponsor, the Core Lab will attempt to perform the assay at the request of the PI, if the utilization of Core Lab resources is approved by the Study Sponsor. If the Core Lab cannot perform the assay in the manner required, a substitute lab will be identified either by the Study Sponsor or the Core Lab may assist the PI in identifying a suitable external lab.

3. NIH-funded, non-CRC studies at Drew: (e.g., NIH grant for an in vitro study awarded to a Drew PI)
All requested hormone assays should be made available, if possible. If the Core Lab cannot
reasonably perform the assay in the manner required, every effort will be made to identify an external lab that is equipped to perform the assay.

4. Non-NIH-funded, investigator-initiated, non-CRC studies at Drew: (e.g., Industry/private grant for an in vitro study awarded to a Drew PI)
   For all hormone assays that will not be run by central labs as determined by the Study’s Sponsor, the Core Lab will attempt to perform the assay at the request of the PI, if the utilization of the Core Lab resources is approved by the Study Sponsor. If the Core Lab cannot perform the assay in the manner required, a substitute lab will be identified either by the Study Sponsor or the Core Lab may assist the PI in identifying a suitable external lab.

5. Any investigator-initiated (NIH- or privately-funded) project conducted primarily at sites other than Drew: (e.g., Industry grant awarded to a Harbor-UCLA PI who requires a specific Core Lab expertise not otherwise available)
   For all hormone assays that require the use of Core Lab facilities in the capacity of a consulting or collaborating lab, the Core Lab will attempt to accommodate the needs of the study, provided that Drew University or the CRC stands to benefit in some capacity from such studies (e.g., prominent co-authorship). However, if the Core Lab cannot perform the assay in the manner required, the Core Lab may assist the PI in identifying a suitable substitute external lab.

6. Studies that do not fully meet any of the above criteria: (e.g., Industry-sponsored, industry-initiated drug trials not using the CRC)
   The Hormone Assay Core Lab will not devote resources toward such studies.

Administrative Requirements and Procedures
All studies utilizing CRC resources must receive prior approval from the RCAC. If the study also requires the services of the Hormone Assay Core Lab, provision of laboratory services will be contingent upon approval of the RCAC. As indicated above, requests for Core Lab services that do not involve a study approved by the RCAC will receive a lower priority.

1. The Investigator will submit the application to the RCAC for formal consideration to use CRC facilities. Any requirements for the Core Lab services must be stated in the submission materials. If the investigator indicates that Core Lab services are needed, the Core Lab Utilization Request Form should be completed as part of this application process, and will require details of the specific analytes, and the estimated number of samples for each assay. If the proposed study requires assays on analytes not stated on the form, the Investigator must concurrently contact the Core Lab staff to discuss the nature of the required assays prior to approval by the RCAC, to ensure that the required resources and facilities can be made available to conduct the assays in the capacity and turnaround time required by the study, and that the correct measurements are achievable. The Core Lab must be provided with a minimum of 4 weeks prior to the scheduled RCAC review of the protocol or prior to the start of the study for non-CRC studies. If the required equipment and/or reagents are not immediately available, the Core Lab will judge the feasibility of providing the requested assay, (if obtaining or accessing the required equipment and/or reagents can be reasonably expected). If establishing the assay is not feasible within the time frame required, the Investigator may be referred to an alternate laboratory, or the Investigator may wish to reconsider their submission to the RCAC to use CRC facilities. The Core Lab does not judge the scientific or ethical merit of the project, and is in no
position to directly approve or disapprove of the proposal. Feasibility of the requested assay is
decided solely to advise the Investigator of any potential limitations that may impede the
successful completion of the study if RCAC approval is ultimately granted.

It is a standing policy of the Core Lab that samples will be batched and stored, and processing
will only occur at the agreed-upon frequency for the provision of results. If the investigator
requires a more frequent, recurring schedule of turnaround for specific assays (e.g., for
screening, randomization, or other interim assessments that dictate a critical decision point), the
frequency must be discussed with Core Lab personnel.

2. **Provision of Core Lab services will not commence until the RCAC has approved the study.** Once approved, the requested assays may begin and continue as needed, until the
acquisition of data is complete. It is hoped that the process of RCAC review, IRB review, and
Core Lab review will occur concurrently, in order to facilitate the timely commencement of the
study without unnecessary administrative delays. For RCAC-approved studies, the following
documentation and procedures will be required for all samples to be processed by the Core Lab:

3. A copy of the **IRB approval letter** (for studies involving human subjects) for the project
must be submitted to the CRC (including off-site IRB approval letter for studies conducted
outside Drew University; or IACUC approval letter for animal studies)

4. **Sample receipt procedures:** All samples must be accompanied by a typed or otherwise
legible listing of the samples, indicating the date, name of the PI, and the project number. For
human samples, **no personal identifying information related to the subject may appear on the sample.** If a personal identifier appears (e.g., name, SSN, DOB, medical record number, etc.),
the sample will be immediately returned to the PI unprocessed. **All PI’s must use anonymous identifiers when labeling their submitted samples.** Confidentiality of subject identities must be
maintained in accordance with IRB and HIPAA regulations. Upon arrival, a representative of the
Core Lab will sign the list as a proof of receipt and to accept responsibility for the samples. One
copy will be returned to the sample bearer and another copy will be kept in the laboratory for
formal entry of these samples into a database registry.

5. **Laboratory records:** All samples received will be logged into a central password-
protected database. Only laboratory personnel will be permitted to have access to this database.
Results, once obtained, will be entered into the database as well.

6. **Release of results:** Provided that **all required documentation** has been received by the
Core Lab, and provided that all **accounts for a given PI are up to date**, results will be released to
the PI according to the frequency previously agreed upon between the PI and the Core Lab as
stated in the Utilization Request Form. If required documentation is not complete or up to date
(e.g., lapsed IRB approval), or if the PI’s account is not up to date (e.g., previously unpaid
invoices), **the Core Lab will withhold assay results until the deficiency has been corrected.**

7. **Charges:** A current list of charges for the Core Lab’s available assays will be maintained
at all times. The Core Lab may revise its list of charges for its services from time to time,
recognizing the need to keep rates competitive, but also accounting for any unique aspects of the
assays that are exclusive to the Core Lab. PI’s will be charged the rate that is in effect at the time
the assay is performed, and not at the time of application or invoicing. In the event of a rate change, every effort will be made to inform PI’s with pending samples that will utilize the assays in question regarding the new rate. However, failure of the PI to receive notification of the rate change does not exempt the PI from payment at the new rate. Invoices will be issued to all PI’s for a given study concurrent with the release of results (at the frequency previously agreed upon at the time of application). All invoices issued to PI’s will be relayed through the CRC Administrator, who will oversee the status of all Core Lab charges and ensure that outstanding charges are ultimately paid in full.

8. Discounts: Rates for Core Lab services will be established in two tiers:
   a) The full rate that encompasses reagents/materials costs as well as an appropriate portion of technician time and laboratory maintenance costs
   b) The Drew rate that encompasses reagents/materials costs only
The Hormone Assay Core Lab was established to support research specifically by Drew investigators. Since the Core Lab operating funds cover technician time and maintenance costs, these charges do not need to be recovered from Drew investigators who use Core Lab services as intended. However, non-Drew investigators who utilize Core lab services do so as outside clients who are taking time away from the Core Lab’s intended purpose, and will therefore be billed at the full rate. In reference to the priorities listed above, the Drew rate will apply to categories 1 through 4. At the discretion of the Core Lab Director, customized rates may be applied for specific investigators that deviate from the set rates. The Core Lab Director may negotiate reciprocity with any investigator in the form of exchanges for concurrent or future services in lieu of financial compensation. In these circumstances, the nature and details of the exchange must be agreed to by both parties in writing, and must be a reasonable exchange of services.

9. Within any given priority category (listed above), samples will be run on first-come, first-serve basis according to the receiving log, depending upon the availability of assay reagents. Studies that do not utilize CRC facilities but do require Core Lab services (e.g., vivarium studies) receive a lower priority. Although the RCAC will not review such studies, the Core Lab still requires Investigators to review the study directly with the Core Lab if the required assays are not listed above, or if they are to be assayed in an animal species not previously assayed by the Core Lab. The Investigator is encouraged to contact the Core Lab staff beforehand to see if Core Lab personnel have had previous experience with a particular animal model. It is understood that IACUC approval for animal studies will occur concurrently with the Core Lab’s review; assays will not commence until documentation of IACUC approval has been received.

10. The Investigator may make any inquiries as needed regarding any of the Core Lab’s assay procedures, or the status of submitted samples.