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POST-AWARD ADMINISTRATION

The following College of Nursing (CON) post-award operating procedures supplements guidelines and/or policies specified by your funding sponsor and/or the University Contract & Grant Administration. Please refer to your award documents for details and appropriate web sites as well as the sponsor’s Grant Policy Statement, if available.

Notice of Funding/Award
When a notice of funding is received, faculty should notify the following individuals:

- Dean
- Associate Dean for Research (ADR)
- Associate Dean for Academic Affairs (ADAA)
- Center for Nursing Research, Scholarship & Innovation (CNRSI) Research Administrator (CRA)

It is required that the PI provide a copy of the full formal notification of award (NOA) to the ADR and CRA immediately upon receipt. It is the PI’s responsibility to provide this information to facilitate set up of a MSU account/subaccount. No spending can occur prior to MSU account set up and IRB approval. It is also required that the PI provide a copy of the Summary Statement from their grant submission. This is essential to help the CRA and ADR work with the PI to adjust the proposal, budget, etc… as the grantor had identified. The PI will meet in person with the CRA and ADR on requests of revision to the project budget by the Grantor. If not already completed, it is required that the PI provide delegate access in eRA Commons to the CRA.

Please note, only the CRA will communicate with the Office of Sponsored Programs (OSP) and only the CRA and OSP will communicate with the Grantor. The PI is expected to only communicate with the CRA, unless extenuating circumstances arise, in which the PI must communicate with OSP and/or the Grantor, in which case the CRA must be included in the communication.

There are times when the University, CON and funding agencies revise policies on disseminations plans, data safety monitoring plans, etc… between the time of submission and funding. Please be aware that the ADR may require you to revise certain pieces of your proposal so they meet current requirements.

IRB Approval
Studies Involving Human Subjects — A MSU account number may be set up with preliminary MSU Institutional Review Board (IRB) approval (45.CFR 46.118). Contact with human subjects may not occur until MSU, CNRSI, as well as external sites who are engaged in research, receives IRB approval of the full protocol. Full IRB applications and the official IRB approval letter for the initial application, each revision, each renewal, closeout, and any ‘other’ filings, including the date of file submission and approval, throughout the entire span of the project must be submitted to the CRA to store in the project folder. It is the PI’s responsibility to ensure their IRB application is kept up-to-date.

It is required that the PI add the CRA to their IRB application as a ‘guest’ and designate as primary contact. At the discretion of the ADR, the PI may be asked to add the CRA and a CON Delegate to their IRB application as ‘study team members’ and designate as primary contact.

Various mechanisms for IRB approval at external sites are available:

- MSU has a process to extend IRB approval to subcontractor sites without a regular Institutional Review Board. The IRB office can assist you to establish an Individual Investigator Agreement with each person/site.
- MSU also has reciprocal agreements in place with various Michigan area hospitals. The process to receive IRB approval at an institution with a reciprocal agreement varies, so you should contact the MSU IRB office for guidance.
If the site has an IRB but does not have a reciprocal agreement with MSU, you will need to submit a full application to both MSU and the site.

ClinicalTrials.gov Registration
By law (Title VIII, Section 801 of Public Law 110-85), the Principal Investigator or designee must register clinical trials on the ClinicalTrials.gov Protocol Registration System Information website. The College of Nursing requires registration for all funded projects. Additionally, the NIH encourages registration of all trials whether required under the law or not, and many journals are now requiring registration as criteria for publication. For more information, please visit: https://clinicaltrials.gov/ct2/manage-recs. The Office of Regulatory Affairs manages MSU user accounts. The PI is required to grant delegate access to the CRA and at the ADR’s discretion, the CON Delegate.

Account Set-up
The CRA will coordinate with MSU’s Contract & Grant Administration (CGA) to receive an account number for your work. Only the CRA will communicate with CGA and only the CRA and CGA will communicate with the Grantor. The PI is expected to only communicate with the CRA, unless extenuating circumstances arise, in which the PI must communicate with CGA and/or the Grantor, in which case the CRA must be included in the communication.

*Note: CGA will not release an account number until the project has Full MSU IRB approval.

Review College Assignment
It is imperative that the PI has open communication with the ADAA in order to properly plan and distribute teaching assignments and obligations. Changes in assignments occur on a semester basis, so it is important the faculty member contact the ADAA upon confirmation from their Program Officer that funding is likely or as soon as the NOA is received. Changes in teaching and/or service assignments should not disrupt the functioning of the College—needs of the students and college must be considered. The PI will also notify the ADAA of other faculty from the College who have teaching assignments and would devote effort to the grant.

Requesting Space
The Associate Dean for Support Services will allocate space upon request. Refer to the College Policy on Assignment of Space, located in the Faculty Handbook. A PDF writable “Request for Research Space” form is available here on the Research Resources section of the CON web site.

Post-Award Meeting—Start-Up Meeting
A ‘start-up’ meeting will be scheduled within 30 days of award (funding and account number) receipt. The following individuals will attend the start-up meeting: The PI, ADR, CRA and Project Manager (where applicable and identified), and at the discretion of the ADR, the CON Delegate. The PI is expected to attend this meeting in person.

Start-up Meeting Agenda:
- Review terms, conditions, restrictions of NOA, sponsor
- IRB approval
- Study timeline
- Participant recruitment
- Review allowable vs. unavoidable costs and spending according to proposal budget
- Staffing your project—Hiring staff
- Compliance training requirements
- Contract staff—Consultants, vendors, & subcontracts
POST-AWARD ADMINISTRATION

✓ Data Collection Sites
✓ Copier, scanner, printer, fax services
✓ MSU IT shared project drive—Requesting a drive, requesting access for staff members
✓ Telephone expenses
✓ Travel
✓ Supply purchases
✓ Additional storage
✓ Data management/storage
✓ Transfer of data to the CON warehouse
✓ CON data archive
✓ Project reporting
✓ Postage
✓ Research incentives
✓ EBS system
✓ Dissemination of materials and study results
✓ Intellectual property
✓ Study procedures
✓ Quality assurance – Recruiter, data collector, and interveners
✓ Adverse event planning/conflict reporting

❖ Study Timeline
The PI is required to adhere to the study timeline or have immediate communication with the ADR and CRA of deviations from the timeline.

❖ Allowable vs. Non-Allowable Costs & Budget
See agency guides for what is considered an allowable cost. For costs to be allowable, they must directly benefit the project(s) being charged and must be reasonable. In addition, allowable project expense must be needed, received, and used within the budget period.

See Federal Cost Policy on the CGA website. For the definition of reasonable and the allowability of common items of cost, as well as NIH guidelines, visit the NIH website for the most recent NIH grants policy statement.

Examples include:
✓ Entertainment costs, i.e., working lunches—not allowed on grant.
✓ Local and cell telephone—should not be charged to the grant unless the phone will be used exclusively for the project, i.e., no employee will ever make a personal phone call.
✓ Office supplies, i.e., wall clocks, calendars, waste cans, paper punches, staplers that might be used for other purposes—not allowed on grant.
✓ Computers utilized only for grant purposes—allowed on the grant.
✓ Project supplies, i.e., pens, folders, notebooks used exclusively for the project—allowed on the grant.
✓ Memberships, Books, and Subscriptions—not allowed on grant.
✓ Travel costs—with a direct benefit to the project are allowed on the grant.

❖ Staffing Your Project – Hiring Staff
Within 30 days of receiving the award and prior to beginning the hiring process, the PI will submit all job descriptions for review and approval to the CRA, ADR and at the ADR’s discretion, the CON Delegate. Upon approval, the CRA will turn in all job descriptions to the CON Human Resources Administrator (HRA), so they may have them on file to assist in hiring throughout the project period. The PI is required to provide the job descriptions to the potential candidate prior to the determination to hire and all project staff will be required to sign their job description before hiring can be finalized.

All hiring paperwork must be processed through the CRA. Once reviewed by the CRA and approved by the ADR, the CRA will pass along the paperwork to the HRA. All changes in employment status of all project staff are required to be reported to the CRA before the action is finalized, i.e. firing of staff member, reducing/increase in hours, change in role,
etc... All communication regarding HR must go through the CRA, who will communicate with the HRA. The PI will not directly communicate with the HRA without the CRA.

- Compliance Training Requirements
  As a recipient of federal research funds, MSU is required to comply with various federal regulations governing the use of human subjects and animals, as well as safety standards governing the use of radiation, chemicals, biological samples, hazardous waste, etc. in research studies. Additionally, federal regulations require that research staff receive training in the responsible conduct of research.

**ALL FACULTY, EMPLOYEES AND VOLUNTEERS WHO WORK ON MSU CON RESEARCH STUDIES (FUNDED & UNFUNDED) ARE REQUIRED TO COMPLETE TRAINING AS SPECIFIED BELOW.** It is the PI’s responsibility to monitor and maintain compliance with training requirements for anyone associated with their research. A copy of Human Subjects certification (IRB), Health Insurance Portability and Accountability Act (HIPAA) & Good Clinical Practices (GCP) certificates for all faculty, staff, students and volunteers working on the project must be submitted to the CRA upon receipt. Project staff may not have contact with participants until the CRA has all three certificates on file. In addition, the PI will provide dates of training sessions for faculty, staff, students and volunteers to the CRA. The PI must keep record of the training for all study personnel and provide the list to the CRA monthly.

<table>
<thead>
<tr>
<th>Training Program</th>
<th>Required for:</th>
<th>Training Frequency</th>
<th>Required Completion By:</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRB</td>
<td>All faculty, all employees, and volunteers.</td>
<td>Initial MSU training tutorial required; renewal available at PI’s discretion.</td>
<td>One week after start date or prior to human subject contact, whichever occurs first.</td>
</tr>
<tr>
<td>HIPAA</td>
<td>All faculty, all employees, and volunteers.</td>
<td>Initial training</td>
<td>One week after start date or prior to contact with human subjects or their identifiable data, whichever occurs first.</td>
</tr>
<tr>
<td>GCP</td>
<td>All faculty, all employees, and volunteers.</td>
<td>Initial training, with refresher every three years.</td>
<td>One week after start date or prior to human subject contact, whichever occurs first.</td>
</tr>
</tbody>
</table>

Instructions to access training modules are included on the Training Tutorial Instructions document.

- **Contract Staff – Consultants, Vendors, and Subcontracts**
  The CRA must be involved in all communication (verbal and otherwise) with consultants, contract staff, vendors and subcontracts. The CRA will work with the PI, the grant administration team from the subcontract site and CGA to establish any subcontracts associated with the study. The University offers three mechanisms for payment of non-campus vendors or staff who work on your project.

**Professional Services Contract**—used for engagement with an individual with a social security number. The contract is for $600 or more in total. Work performed by an independent contractor (IC), should be requiring specialized knowledge or experience, where MSU has no control over how the work is done just the final product. This form should be completed (and finalized in EBS) before work commences.

Should be used if:
- Work that involves intellectual property, i.e., someone will be creating something for you such as a website or programming, and you want to ensure you will own the property afterward.
- Project recruiters and consultants.
POST-AWARD ADMINISTRATION

Should not be used for:

- Employment of staff who do not provide similar services to the general public. It is a federal violation to hire staff using the Professional Services Contract.

Purchase Order (PO)—A PO is a type of contract for goods or services that commits the supplier and university to a buying transaction. POs are one of the primary buying methods at MSU and are appropriate for goods, equipment, and services not available through the University Stores, strategic contracts, Open Orders, or by using the Pcard. Purchase Orders should be completed (and finalized in EBS) before work commences.

Purchase Orders are created without PSCs to procure services or materials from businesses. A quote or statement of work (including a budget) should be attached to a Purchase Requisition, submitted through the MSU EBS system. The amount of the purchase order is encumbered when the PO is prepared. MSU Accounts Payable applies invoices to the encumbrance as they are paid.

Should be used if:

- Vendors providing a service, e.g., transcription, website development, data management, or if purchasing software.
- Vendors working with human subjects as long as they are not “engaged in research,” e.g., passing out fliers, referring subjects to contact MSU for more information. The MSU Human Research Protection Program (HRPP) can assist with the determination of whether a vendor is engaged in research.
- Subcontractors engaged in research for funded projects. The PI or project manager should provide a statement of work and budget for the work that will be completed by the subcontractor, along with the name and address of the person to whom the subcontract should be sent for signature. The CRA will facilitate preparation and approval of a subcontract agreement.

Disbursement Voucher (DV) – A DV is used to pay for goods and non-payroll services when a requisition and PO are not appropriate or required due to the nature of the payment. DVs are usually used for one-time payments or reimbursements. To receive payment via DV, payees must be either an MSU employee, Disbursement Voucher vendor, Special Payment vendor, or Purchase Order vendor.

Should be used for:

- Refunds and reimbursements, including travel and out-of-pocket reimbursements.
- Payments for supplies are totaling $2,500 or less NOT purchased through University Stores.
- Honoraria, speaker fees, and performer payments.
- Conference registration fees when a MSU Purchasing card is not accepted.

Should not be used for:

- Situations that require a requisition and purchase order, as the use of a DV does not replace the normal purchasing procedure.
- Service payments to enrolled students.
- Recurring payments such as equipment rentals and maintenance repairs.
- Situations were a MSU Purchasing Card is accepted and appropriate.
POST-AWARD ADMINISTRATION

Data Collection Sites
At the ADR’s discretion, the PI may be required to involve the CRA in all conversations with data collection sites.

Requesting a Cannon Copy/Scan/Printer Code and Fax Service
The Cannon machines located in the A-wing and C-wing of Life Sciences require an ID to copy, scan, or print. See the CRA to request an ID. MSU IT may need to set up a scan folder. The CRA will contact the Administrative Assistant for Support Services to request an authorization code for you to access the Cannon copiers for your project needs.

You may receive faxes through the Cannon copier/scanner/fax/printer; however, this method should not be used for confidential or sensitive information, e.g., consent forms. MSU has contracted with a third party fax provider (MaxEmail.com) to provide secure virtual fax services (master agreement #133424). Please work with the CRA to setup this service.

Data Security/Requesting a Shared Drive Project Folder
Your data should be stored on a secure network drive with appropriate back up and intrusion protection. Often, secure space is provided by your data management team, e.g., BRIC; however, a secure network drive you and your in-office research team can access will be required. Project drives will be set up as requested by the CRA on the N Drive. Only those identified to have access to the folder on their hiring forms will have access. At the discretion of the ADR, the CRA and CON Delegate may be assigned access to your drive. Please note, this is a separate drive from your MSU IT P Drive—under no circumstances are project data to be store on the PI’s P drive, personal computer/laptop, or personal hard drive/flash drive; as these entities are NOT routinely backed up. It is required that the PI follow best practices for security and confidentiality of their data.

Hardware & Software Purchases
Computer hardware (PCs, monitors, printers, etc.) and standard software (Office, Antivirus, Adobe, and Internet Explorer) must be purchased through MSU IT (via AISS) to ensure computers, printers, and software are compatible with our systems and will be supported. Please work with the CRA for any of these needs.

Telephone Expenses
Coverage of telephone expenses is required for funded research. There are four options to cover telephone expenses.

Requesting a Long Distance Access Code—If you will need to make long distance calls from any of the Bott building conference rooms on the 2nd or 3rd floor, you will need a long distance access code from Support Services. See the CRA to request a long distance access code. An MSU subaccount number is required to request a long distance access code. MSU Telecomm will charge your account directly each month. It is important that the proper project codes are used (if you have multiple projects), codes are cancelled when the project ends, and your staff no longer uses the code once the project ends. The CRA will cancel the code upon project completion.

University Calling Cards—If staff will be completing calls on behalf of the project from off-campus, MSU Calling Cards are available through Telecommunications. If using an MSU calling card, calls may be placed using the calling card and charges will automatically be billed to your grant account. You will be liable if staff you have employed place inappropriate calls using this card.

Pre-paid Calling Cards—An alternative to University calling cards may be pre-paid phone cards, although staff need to ensure sufficient minutes remain on the card to complete the call.
POST-AWARD ADMINISTRATION

Zoom—Zoom is the preferred MSU method. Go to zoom.msu.edu and log in with your netID and password. Click on meetings (left tab), click on schedule a new meeting, enter the topic information and date and time to start (generally, start 30 minutes earlier than scheduled time and add another hour at the end in case the meeting goes over the allotted time), scroll down to enable join before host and click that box; hit save. Click on the outlook calendar, which gives you the details of your meeting and includes regular phone call-in information as well as video information. Share this information with all attendees. For further assistance with zoom set up, please contact the Academic Technology Coordinator.

Travel

CON Absence from University Form—CON faculty must complete a CON Absence from the University form prior to travel if they are actively conducting research or receiving funds from the CON (academic year, summer or sabbatical), regardless of whether travel is for MSU business or personal (see CON Travel Policy in faculty handbook).

- Coverage for your research project must be indicated on the absence form.
- If absence is extended, e.g., greater than two business days, research coverage must indicate a faculty or full-time staff person who can be contacted in case of emergency. On-call or student staff are available limited hours and are not appropriate to leave in charge. The person in charge should be able to make decisions in your absence if needed—this is often a Co-Investigator or Project Manager.
- If a faculty or full-time staff person cannot be identified, the CNRSI Coordinator or ADR can serve as the emergency contact/staff supervisor during the PI’s absence.
- Phone messages should indicate hours the project phone will be answered and who to contact outside of those hours for emergencies.

Completed forms should be submitted to the CRA, who will obtain approval from the ADR.

MSU Pre-trip Authorization—All persons traveling on MSU business must complete a University Pre-trip Authorization prior to travel. The MSU Controller website has helpful information concerning University Travel and Reimbursement. Pre-trip authorization is not required for non-MSU business travel, e.g., outside work for pay, personal travel. Completion of travel forms is the responsibility of the faculty member or their designee for themselves as well as their research staff.

A blanket Pre-trip Authorization for a year (1/1 – 12/31) must be processed for routine in-state trips that do not require an overnight stay. It is the responsibility of the PI to submit to the CRA a blanket Pre-trip Authorization for him/herself and all of their research staff within the first week of hire. The CNRSI tracks expiration dates of blanket Pre-trip Authorizations as a courtesy to alert faculty when a blanket authorization will expire, but the PI needs to track this as well.

MSU Travel Expense Report—All persons traveling on MSU business must complete a MSU Travel Expense Report upon completion of travel and submit it (along with all receipts) to the CRA in order to receive reimbursement.

International Travel—Please see the CRA if you plan to travel Internationally for your research as there are specific University Policies to be aware of. Please refer to the MSU Manual Business Procedures, Section 70 for information on domestic and international travel.

Visitors to Campus—Room reservations for visitors may be made at the following hotels and charged to an MSU account number.

- Kellogg Center, S. Harrison Road, East Lansing, MI 48824; (517) 432-4000.
POST-AWARD ADMINISTRATION

- Candlewood Suites at MSU, 3545 Forest Road, Lansing, MI 48910; (517) 351-8181.

**Visitor Parking**—Visitor permits are available for 2 hours, 4 hours, or 24 hours. The cost is $1.50, $3.00, and $6.00 respectively. Permits may be ordered in lots of 10 from Department of Public Safety.
- To receive permits by mail, email Lupe Dominguez at dominguezg@police.msu.edu. Your email must include type of permit, how many, department name, account number, mailing address, and PI name (to approval charge in EBS). Please note that if you request passes, you must request in blocks of 10.
- To pick permits up in person, see a cashier in the DPS office. Questions can be directed to Lupe at extension 2-1604.

**Supply Purchases**

**Book purchases**—Orders should be placed with a MSU Bookstore when possible so the MSU account can be billed directly. These books must be justified for the use of the project and categorized as allowable expenses. Please work with the CRA should this need arise.

**Supplies**—The PI is required to work with the CRA for purchasing project supplies on their project account/subaccount. The PI may not directly purchase anything for the project. Supplies from the general CON supply room will never be utilized for funded projects. Supplies should be purchased through MSU Stores when possible to take advantage of special discounts negotiated by MSU Purchasing. OfficeMax also provides discounted products if not available via MSU Stores.

**Other Items** not available through MSU IT, the computer store, a MSU bookstore, or MSU Stores may be purchased via:
- **MSU Purchase Requisition**—These must be processed through EBSP by your Project Manager or the CRA.
- **Reimbursement**—With approval from the ADR, you can purchase the item and submit for reimbursement through the EBSP system. Your Project Manager or CRA should initiate the eDoc to request reimbursement.
- **Procard**—This program has been designed to allow for the direct procurement of low-value, small dollar, and/or recurring purchases by the end user through the use of a credit card. The intent is to eliminate the need for multiple small dollar requisitions, reimbursements, etc. If you anticipate needing a high-volume of materials that cannot be routinely ordered through MSU Stores (such as a secure fax service, monthly Wi-Fi fees for data collection computers), you may wish to consider requesting a Purchasing Card (PCard). All request for PCards must be directed to and approved by the ADR.

If approved for a PCard, you will be required to attend a training session on appropriate and acceptable use of the card. Once you start using the PCard, you will need to upload a copy of each receipt in the EBSP system. The PCard should not be used to purchase from vendors MSU has negotiated rates with (see Purchasing’s website for a list of MSU approved vendors).

Useful vendors for supply purchases include University Stores and Spartan Marketplace.
- University Stores – A warehouse facility where commonly used, high-volume items are stocked and distributed. Because University Stores is a major warehouse located on campus, it consolidates the university’s power and includes contracted pricing, free delivery, consolidated billing, easy returns. Commonly purchased items through University Stores include office supplies, non-specific research items, and shipping supplies. University Stores purchases can be placed through Spartan Marketplace.
- Spartan Marketplace – An online procurement solution, accessible through EBS, that allows MSU employees an easy and effective way to order department supplies from certain supplies at contracted prices. This allows specific purchases through specific vendors like Apple, Dell, and Office Depot to be charged directly to accounts effectively and at lower prices.
Michigan State University is exempt from the payment of sales and use taxes on purchases of tangible property and applicable rentals. When purchasing through MSU, tax exemption can be completed two ways:

- Direct purchases by MSU, including direct vendor payment with the Michigan Sales Tax Certificate of Exemption. Please note that this certificate cannot be used when an employee makes a purchase with personal funds and then seeks reimbursement.
- Online purchases when using a MSU PCard. Some online purchasing avenues, like Amazon.com, allow you to create a business account and tax exemption may be set up.

Please note: all supplies and equipment purchase with grant funds must only be used to support the study for which the funds support.

- **Additional Storage**
  Limited storage space of non-confidential items (such as additional supplies, incentives, etc.) is available within the College of Nursing. Please see the Administrative Assistant for Support Services to initiate this request. Short-term needs can often be accommodated; for longer-term needs, e.g., more than three months, you may need to consider off-site storage of these items at MSU Stores. MSU Surplus rents 4’x4’x4’ bins for a monthly fee of approximately $16. Fees are billed to an MSU account number monthly. To arrange for storage, contact Bill Grice, Stores Receiving, Angell Building, 166 Service Road, (517) 355-1700 or gricew@msu.edu.

  Additionally, the high-density room should be utilized for the storage of documents and information. The Associate Dean for Support Services assigns space in this room. At the ADR’s discretion, the PI may required to provide access to all data storage areas to the CRA.

- **Data Management**
  Data collection/management resources are available on-campus within MSU BRIC. If data is collected and maintained outside of BRIC, procedures must be in place to protect the data (See [MSU – Data Storage Guidelines](#) for additional policy information). Storage of data on laptops should never occur; they are NOT routinely backed up, are easily accessible, and may be stolen. At the ADR’s discretion, the PI may required to provide access to all data managements systems to the CRA.

- **Storage of Data and Confidential Files**
  Both paper and electronic data files, and confidential files (i.e. consent forms), must be retained following IRB approved procedures and per sponsor retention policies (typically three years from submission of the final report). The CNRSI can provide storage for non-active research files until the discard date. Secure electronic file space is available on campus through BRIC, if using BRIC for data management, or through MSU IT. Both BRIC and MSU IT provide back up and intrusion protection. The CRA can assist with requesting a MSU IT share drive if needed.

- **Transfer of data to the CON Data Warehouse**
  The data warehouse is a digital drive for the storage of funded & unfunded project data. Only the CNRSI CRA, the ADR and the CON Statistician have access to this drive. The data on this drive will be kept according to storage guidelines and available for further usage.
CON Data Archive

The PI will schedule an in-person meeting with the CON Statistician, ADR, CRA, and at the discretion of the ADR, the CON Delegate within 30 days of receiving the notice of funding, to discuss a plan to archive data throughout the duration of the study. The PI is required to follow and comply with the CON Data Archive policy.

CON Data Archive Rules & Regulations — The University is accountable for the proper maintenance and availability of all primary research data created or collected by university personnel. University personnel does not only include employees of the university, but also students who, as part of faculty supervised research (i.e. theses and dissertations), gather and analyze research data. Sponsors of university research, federal and state oversight agencies, or journals and other colleagues in the field may need or be legally entitled to review primary research data well after publication or dissemination of results.

At MSU, research data is normally retained in the unit where it is produced, e.g., departments and colleges. Research records must be retained on the MSU campus or in facilities under the auspices of MSU unless the Vice President for Research & Graduate Studies (VPRGS) grants specific permission to do otherwise. In order to comply with these efforts, the CON has set up a data warehouse, which is to retain all primary research data collected by CON-affiliated researchers. This includes (a) all primary research data from projects of funded grants for which a CON member is the PI, and (b) all primary research data collected as part of an unfunded project, e.g., a dissertation, thesis or unfunded faculty research, for which a CON member is the PI or supervising faculty. Note: For dissertation or thesis data, the faculty advisor/supervising faculty is the PI of the project.

Research data are defined as the recorded information, regardless of the form of the media on which it may be recorded, necessary to support or validate research findings. Included in the definition of research data are laboratory notebooks, as well as x-ray film, photographs, negatives and slides, print outs, video and audio tape, computers and computer data storage devices, synthetic compounds, organisms, cell lines, viruses, cell products, cloned coordinates, plants, animals and spectroscopy data, and all other products generated from research, however recorded or preserved.

Other than circumstances where the IRB has given special permission, IRB policy states research data must be retained for a minimum of 3 years following the last project report or publication, unless one of the following circumstances justifies longer retention:

- Data must be kept for as long as may be necessary to protect any intellectual property resulting from the work
- If any charges regarding the research arise, such as allegations of misconduct in research or financial conflict of interest, data must be retained until such charges are fully resolved
- If a student is involved, data must be retained at least until the degree is awarded or it is clear that the student has abandoned the work.

The College of Nursing has specified that de-identified electronic research data will be stored beyond the IRB required 3-year period of retention. De-identified electronic research data will be maintained in the archive indefinitely to provide additional opportunity for others (students and faculty) to use the data for investigative purposes. Other types of research data will be destroyed after the 3-year minimum, unless under one of the above circumstances where the data needs to be archived for a longer period. The CON will maintain a permanent record of research data stored in the archive, both electronic and hard-copy. Additionally, CON will maintain a permanent record of hard copy data that are destroyed and the destruction date.
POST-AWARD ADMINISTRATION

Information to be housed in the CON Data Archive—In addition to fulfilling the legal minimum requirements for sound data archives, the purpose of the CON Data Archive is to house data sets that can be used by new investigators for secondary analysis. This necessitates certain standards of documentation that all archived data sets should follow.

The primary data should be accompanied by:

(A) Analytic Guidelines, which provide the following information:
   a. An outline of the original study’s aim and research hypothesis (can be taken from the original proposal).
   b. A short description of all data files and data sources containing data collected in the study, e.g., numerically coded information for statistical analysis purposes, audio and video files, biological specimen and results from laboratory tests, etc.
   c. Information on original target population, recruitment strategies, and study sample, including, if applicable, the sampling design (e.g., convenience, purposive or probability sampling) and the units of analysis (e.g., individuals, households, care organizations, etc.).
   d. A short description of the research design (e.g., cross-sectional, longitudinal, experiment/intervention, observational, focus groups, qualitative interviews, etc.).

(B) A codebook for numerical files listing all variables and pertinent value labels; if already established, transcriptions of audio and video files; a codebook and documentation for numerical files containing laboratory results, other physiological data, and a copy of all the instruments that are included.

(C) Primary data files containing numerical information from interview data, laboratory tests, biometrics, etc. as well as transcriptions of qualitative interviews or observational notes; original video and audio files also need to be included. Before submitting data to the CON archive, researchers should inquire about acceptable software formats (e.g., SPSS, STATA, SAS, Excel, for numerical data or NUDIST, ATLAS for qualitative data). **Note:** Primary data includes the information as originally collected and coded.

(D) If applicable, the data should include analytical files, which include transformed and newly created variables on the basis of primary data; analytical files must be accompanied by the commands that incorporate the data transformations (recoding, scale computations, etc.).

(E) List of references based on the data in the archive.

❖ **Fidelity**

Fidelity is the principle of administering an intervention consistently to research participants. All PI’s should follow their devised protocol stringently to ensure research fidelity.

❖ **Project Reporting**

**Monthly Financial Reports**—The CRA will prepare and distribute financial reports monthly showing charges and encumbrances against your account. If an error is identified, please see the CRA ASAP. The PI must be aware of spending, encumbrances, and projections. Additional documentation will be required to correct errors if more than 90 days have elapsed since the error was incurred.

**Effort Reports**—An electronic system calculates your effort bi-annually on each account number based on appointment papers processed during the period. PI’s and MSU staff receive an email notification when their effort report is ready for review and certification. PI’s and MSU staff must carefully review the report to confirm that the effort shown is accurate; appointment paper changes processed only a few weeks prior to the period end date may not be reflected in the electronic report. When this occurs, the PI/MSU staff member should adjust their reported effort prior to certifying. PI’s will be required to certify effort for all hourly and/or Graduate Assistant staff. The PI must complete effort reporting by the due date set by MSU.
Postage Expenses
Mail can be sent via the U.S. postal service or via an express mail provider. All postage needs will be coordinated through the CRA.

Research Incentives for Subjects
Documentation—When gift cards or other non-cash gifts are purchased, detailed receipts and clear documentation of the business purpose must be included. Documentation must also include a disbursement log detailing recipient name, address, amount, purpose, date distributed, and signature of recipient. Recipients are required to sign for all incentives. In cases where signatures cannot be obtained, a detailed explanation must be included in the documentation as well as the date. University policy requires documentation to be retained by the PI for the remainder of the current year plus an additional six years. Research participation incentives offered to anonymous participants (where documentation cannot be maintained in order to preserve anonymity) should be discussed with the ADR and the CRA.

Research Incentive Options—The following options are available for research participation payments. PI’s are required to work with the CRA for all options.

Cash: Cash advances are available through the MSU Controller’s office. Individuals applying for cash advances must sign a promissory note accepting fiscal responsibility for the funds. The minimum amount for an advance is $300. The Cashier’s office should be notified at least two days prior to the desired pick up date if the cash advance requested will greater than $5,000. Typically, cash advances need to be reconciled with the Controller’s office within 90 days. There is a $15 processing fee for requesting cash advances.

University Checks: A University Check can be requested. Participants need to be set up as a Special Payments vendor in the MSU EBS system. Name and address are required for this type of vendor. Once approved by Purchasing as a Special Payments vendor, a Disbursement Voucher can be submitted to pay for research participation. The University will issue a University check and mail it via USPS to each participant. Be aware that University records are public property and confidentiality may be an issue.

If a single cash payment is over $150, the recipient’s Social Security Number must be collected. In this case, you would set them up as a standard vendor (DV) and enter their SSN.

Gift Cards: When using gift cards, investigators are encouraged to send electronic gift cards from retailers, such as Amazon or Target, which can be purchased online and delivered via email. Receipts will be used for documentation of gift distribution. Remember, most VISA, MasterCard, and American Express cards charge an upfront fee to purchase the card and many cards charge a service fee after a certain number of months, reducing the value of the card. MSU Pcards cannot be used to purchase gift cards for volunteers or guests; however, payment for research participation is not considered a ‘gift.’ When purchasing physical gift cards, you may use an MSU Pcard or, if you do not have a Pcard, through a Disbursement Voucher (see the CRA for more information).

Note: If you plan to use cash, University Check, or gift cards, consider disclosing that you are doing so in your informed consent as well. Certain MSU CON administrators, internal auditors, and the MSU Controller may have access to subject information and identity to confirm distribution of the payment.

Research Incentive Storage—MSU Internal Auditors require segregation of duties related to the purchase, storage, and distribution of cash and gift card purchased incentives. The PI must work with the CRA to formalize a plan. For example, if the CRA purchases and secures the incentive, another person must distribute the incentive. The CNRSI has a safe
POST-AWARD ADMINISTRATION

located in the CNRSI Coordinator’s office that must be used to secure cash or gift cards. Research incentives must be placed in CON custody within 24 hours of purchase and may be removed the week they will be distributed.

Tax Implications—Cumulative payments to any one participant greater than $600 across the calendar year will require SSN/tax information for the vendor. This is tracked by the MSU Accounting office. The accounting office may contact the department to request SSN/tax information of the vendor if the current payment request will push the payment to the participant >$600.

❖ EBS System
Form Processing—All financial paperwork is processed electronically using the Enterprise Business System (EBS). MSU staff can request access to the EBS system and receive training on preparation of forms to process expenditures. The CRA will coordinate with the CON Business Office to request access for project employees to the EBS system when needed.

Form Routing and Approval—The CON CRA will submit Financial eDocs for awards on the designated account, ensure that the costs are allowable, and verify that funds are available in the budget line item to cover the cost. Financial eDocs for are then routed to the PI, before being automatically routed to the CON CRA, who serves as the fiscal officer. After CRA approval, the eDoc will automatically route to the CON Fiscal Administrator for approval. The PI is required to approve all financial transactions in EBS within 5 business days of notifications of need for transaction approval.

❖ Dissemination of Materials and Study Results
Logos vs. Visual Identity—The MSU CON logo must be included on materials distributed for your project. The CON Communications Manager should be consulted for how to position the logos according to University policies. Individual project logos are not allowed; however, artwork may be allowed on print materials along with the MSU logo.

Posters and Presentations—The CON has developed templates that should be used for all posters and/or presentations. Templates are available on the Faculty & Staff Resources share drive. There are various options available for poster printing, please see the CRA for these details. Funding for these services should be paid on the grant.

Publications—Publications should follow the Authorship Guidelines. Faculty members are responsible for providing the Research Secretary with a copy of their publications. External and internal reports will be prepared using the information on file in the CNRSI.

Funding Agency Acknowledgement—All materials, publications, and presentations should acknowledge MSU, provide an acknowledgement of funding support, and a disclaimer such as: “This project described was supported by a Grant from the (sponsor’s name). The content is solely the responsibility of the authors and does not necessarily represent the official views of the (sponsor’s name).”

Please note: All dissemination of study materials and results must follow college policies. At the discretion of the ADR, the PI may be asked to provide all dissemination materials to the ADR for approval, prior to that information leaving the CON. This includes manuscripts, posters, abstracts, reports, protocols and presentations.

❖ Intellectual Property
Copyright—The University owns materials and patents developed by MSU faculty unless the University has disclaimed ownership (See University policy here for details).
The **MSU Copyright Policy** contains frequently asked questions to clarify the MSU Copyright policy.

**Study Procedures**
The PI is required to share with the CRA all study policies and procedures. Any change in study policies and/or procedures will need to be approved by the ADR and at the discretion of the ADR, the CON Delegate.

**Quality Assurance**
Quality assurance policies and procedures must be developed and approved by the ADR and at the ADR’s discretion, the CON Delegate, for recruiters, data collectors and interveners prior to the state of the study.

**Adverse Event Planning & Reporting**
The PI is required to create a form for identifying and reporting adverse events consistent with GCP and clinicaltrials.gov. The PI will immediately report any adverse event or conflict of interest to the ADR, CRA and at the discretion of the ADR, the CON Delegate.

**Quarterly Meetings**
Quarterly meetings will be scheduled following the start-up meeting for the duration of funding. Those in attendance will include the ADR, CRA and at the discretion of the ADR, the CON Delegate. The PI is required to attend these meetings in person. The purpose of these meetings are to support university and federal recommendations for research oversight, and to assure that all clinical and clinical trial research and data generated by CON faculty and students are high quality, reliable, and verifiable.

**Quarterly Meeting Agenda:**
- Review of budget and spending in relation to funding
- Review compliance with required training for all project staff
- Review status of IRB
- Review progress report submission due date
- Review no cost extension process (if spending is not per budget)
- Review data and safety monitoring
- Discuss any conflicts of interests
- Discuss data collection site relationships
- Review Quality Assurance Report

**Quality Assurance Reports**
Quality assurance (QA) involves engaging in good data management activities. This includes checking the integrity of data storage and examining frequency distributions to look for project anomalies that threaten the integrity of a study. Project meetings with data collection staff will take place quarterly or on an as needed basis. Quality assurance reports will be prepared and provided to the ADR, CRA and at the discretion of the ADR, the CON Delegate, on the 1st of every month by the PI and study statistician. For reports that fall on the same month as the Quarterly Meeting, Quality Assurance reports will be provided to the CRA at least 1 week prior to the meeting date. The ADR and CRA have the right to request data and documents from the PI as needed, should they feel there are quality assurance issues. The PI will provide all requested materials to the CRA by the deadline given.

**Monthly QA Reports will include:**
- Any change in study aims or outcomes
- Any changes to all study procedure manuals
Research Quality Assurance (Data & Safety Monitoring)
The College of Nursing at Michigan State University has implemented a Research Quality Assurance (RQA) Group comprised of the ADR, CRA, a senior level researcher, a junior level researcher, and an appropriate methodologist with the expertise to provide appropriate oversight and advice. The frequency of review is determined based on degree of risk, i.e. experience of the PI, single vs. multiple accrual sites, complexity of study. This group will monitor and oversee the study, as well as consider factors external to the study when interpreting the data, such as scientific or therapeutic developments that may influence the safety of the participants or the ethics of the study. The group will also review any changes needed to the consent form or study protocol, and conflict of interest issues that might arise during the study. An initial RQA meeting will take place within 3 months of receiving the award. A follow-up RQA meeting will occur 9 months post initial meeting, and then as needed as determined by the RQA committee, but at least annually. The PI must appear in person to the RQA meetings and must participate in all meetings as the RQA Committee sees appropriate to hold. The PI will be required to work with the CRA to provide materials on the date they have been requested by the CRA. The PI will report any changes to study procedures deemed necessary by the RQA to the appropriate IRB offices and funding agency. Please consult the RQA policy manual, which can be found on the CON website, and the CRA for more details.

Progress Reports and Final Reports
Writing progress reports is the responsibility of the PI. Reports must first be submitted to the CRA. The ADR, CRA and at the discretion of the ADR, the CON Delegate, will review the progress reports before submission. The CRA will also file the progress report in the project folder on the N Drive. Refer to your funding NOA for specific instructions on completing the progress reports.

No-cost Extension & Carryover Requests
It is expected that all CON research and educational grants or contracts will be implemented based on the agency approved project timeline. Post-award support will be provided to monitor spending and to identify when spending/work does not occur according to the project timeline so that problem solving can occur early.

CON recognizes that projects are occasionally delayed due to extenuating circumstances beyond the PI’s control. When efforts to complete a project according to their proposed timeline fail, it may be necessary to request a no-cost extension (NCE). A NCE gives the PI extra time to complete the scope and objectives of the project without additional funds provided by the sponsor. A NCE may not be requested for the sole purpose of spending remaining funds. If a NCE is needed, the PI, in collaboration with the CRA, should review the RFP or NOA to determine whether the sponsor will allow a NCE on the funded project, and the process to request an extension. If allowed, the PI, in collaboration with the CRA, should develop a budget to expend remaining funds during the NCE period. The PI should also prepare a written narrative including: a description of the reason for the delay, a summary of the plan for completing the work, a timeline, and an assessment of how the extension will affect the scope/objectives of the project. The written request and budget must be submitted to the ADR for review. This should be completed approximately three to four months prior to the end of the project period. The ADR will discuss the request with the Dean, who will assess the impact of the request on
CON resources and on the needs of the college, and make the final decision on whether to submit the request for no-cost extension. All NCE requests must be reviewed by the ADR and approved by the Dean prior to submission of the request to the sponsor. If approved by the Dean, the CRA will submit the request to CGA, who will submit to the sponsor/funding agency and follow up until a decision is received.

The ability to electronically submit a carryover request to NIH is available through the Prior Approval module in eRA Commons. Carryover allows leftover, unobligated grantee funds to be carried over from one budget year to another and may require permission be obtained from the awarding IC.

The Prior Approval module currently supports the electronic submission of the following requests:
- Change of PD/PI
- NCE requiring Prior Approval

Only a Signing Official (SO) will be able to initiate the carryover request.

- When is a grant eligible for a carryover request?
  - The grant does not have expanded authority.
  - The project period has not ended or the institution requesting additional time has submitted a no-cost extension (NCE) request.
  - The grant is not in close-out.
  - The grant has not been closed.

- What information will an SO need to provide for a carryover request?
  - The carryover request form requires:
    - Amount of funds to be carried over
    - Explanation of unobligated balance
    - Detailed Budget
    - Scientific Justification

Note: If the SO wants to initiate a NCE request in tandem with the carryover request (and it is within 90 days of the project period end date), a button will allow the SO to do that without searching for the grant again. Any clarifications and back and forth between the SO and the program official will occur outside of the system.

Additionally, please note the subsequent review and approval process remains the same.

**Close Out Meeting**
A close out meeting with the PI, ADR, CRA and at the ADR’s discretion, the CON Delegate, will be scheduled approximately 90 days prior to the end of funding to review close out requirements. The PI is required to meet in person.

- **Close-out Agenda:**
  - Review spending in relation to funding—estimate whether funds will be fully expended
  - Review final report submission requirements and due date
  - Review dissemination of materials and study results procedures
Final Reports

**Narrative**—Writing the required narrative report is the responsibility of the PI. Reports must be submitted to the ADR, CRA and at the ADR’s discretion, the CON Delegate for review prior to submission to the grantor. A copy will also be kept in the project folder on the N Drive.

**Financial**—The CRA will work with CGA reports group prepare the final financial report.

Resources

The CNRSI provides support and resources for all projects. There is a CON editor available to assist with editing of manuscripts, posters, abstracts, presentations, etc... Statistical support is provided through the CON statistician. We have visiting scholars who can assist in manuscript development/editing, trouble-shooting, etc... The CNRSI also has multiple students at varying levels that can assist. In order to request any of their services, please go to the CON College Resources website and complete a service request form.

Process for determining statistical support with CON statistician:

1. The CON statistician will meet with the CON faculty member to determine the research question and negotiate analysis needs versus wants.
2. For needs that the CON statistician cannot meet, the CON statistician and faculty member will work together to create a one-page document describing the needs.
3. This document will then be submitted to the Professor of Epidemiology and Biostatistics and Statistics Director, and a working agreement will be negotiated with a faculty member of the Department of Epidemiology and Biostatistics in order to complete the requested statistical analysis.

**Please note: If you are having difficulty accessing any of these resources, please contact the Associate Dean for Research or the CRA for assistance.**

Other Information

- **Meetings & Communication with the ADR & CRA**
  All meetings will be conducted in person. For the CNRSI to be as effective as possible in its effort to support the CON, we ask that the PI please set up meetings should a need to speak in person with the CRA and/or ADR arise. Email is the preferred method of contact if there is a quick question to be answered. Thank you for your assistance in this.

- **ADR & CON Delegate Meeting Attendance**
  The ADR may delegate to the CON Delegate attendance at any meeting without approval from the PI.