Research Development Office Updates

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DIRECTOR OF FACULTY RESEARCH DEVELOPMENT
UNM HSC OFFICE OF RESEARCH

RDO Vision

Expand UNM's capabilities to discover and share new knowledge and promote transformative growth in research, education, clinical care, and health equity in New Mexico

- Promote research career training, planning, and mentorship
- Facilitate interprofessional and interdisciplinary collaborations
- Help with identifying funding opportunities
- Provide navigation for facilities and resources
- Support grant writing

https://hsc.unm.edu/research/research-development/

Research-in-Progress (RIP) Meetings

- Meets on the 3rd Thursday of the month, 3:30-4:30 pm
- Open to all UNM faculty and fellows (all disciplines)
- Designed to provide peer feedback on research products, including in progress grant sections and manuscripts
- Participants sign up to present and discuss their work
- Great opportunity to share resources and connect with potential collaborators

Sign up here! Email HSC-RDO@salud.unm.edu for more information

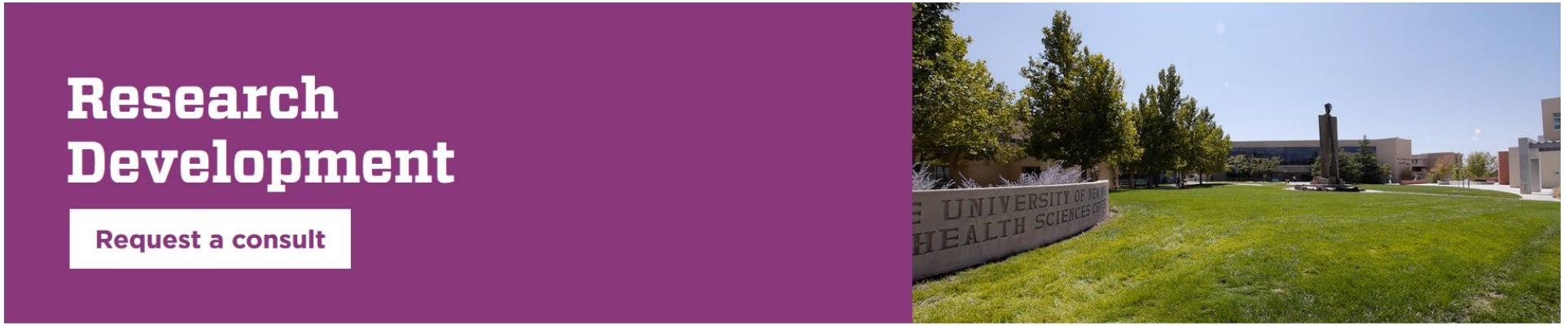
Research in Progress: Core Principles

Collaborative space to give and receive input from expert colleagues

- Active Engagement
- Respectful
- Constructive feedback
- Confidentiality

Questions & Requests

- Kara McKinney
  Strategic Support Manager
  kmckinney@salud.unm.edu
- Request Form:



FDA Guidance on Clinical Decision Support (CDS) Software

BRAD DOLIN, JD

HUMAN RESEARCH PROTECTIONS PROGRAM DIRECTOR

Introduction

- The FDA regulates software that meets the definition of a device, including software providing decision support for diagnosis, treatment, prevention, etc.
- The 21st Century Cures Act (Cures Act) amended the Food, Drug, and Cosmetic Act (FD&C Act), excluding certain software functions from the device definition
- This guidance clarifies the types of Clinical Decision Support (CDS) software functions excluded from the device definition by section 520(o)(1)(E) of the FD&C Act and therefore not regulated by the FDA.

Definitions

- **Device** - a broad range of instruments or articles (including software) intended for medical purposes, including diagnosis, treatment, or affecting body structure/function, excluding those that achieve their primary purpose through chemical action or metabolism, and also excluding certain software functions.
- **Clinical Decision Support (CDS) Software** - a tool that provides healthcare professionals and patients with relevant, personalized information at appropriate times to improve health and healthcare decisions. Essentially, it is software designed to guide clinical choices by delivering knowledge and patient-specific data.

4 Criteria for when CDS software are excluded from the definition of device

Section 520(o)(1)(E) of the FD&C Act outlines four criteria for CDS software functions to be excluded from the device definition. The software must meet ALL of the following:

1. **Not** intended to acquire, process, or analyze a medical image, signal from an in vitro diagnostic device (IVD), or pattern/signal from a signal acquisition system.
2. **Intended** for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information.
3. **Intended** for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition. And;
4. **Intended** to enable a Healthcare Provider (HCP) to independently review the basis for recommendations so that the HCP does not primarily rely on them to make a clinical diagnosis or treatment decision.

Criterion 1:Data Input

- “Not intended to acquire, process, or analyze a medical image, signal from an in vitro diagnostic device (IVD), or pattern/signal from a signal acquisition system.”

- These do NOT meet the exemption:
  - Software functions that are intended to acquire, process, or analyze a medical image, a signal from an IVD, or a pattern or signal from a signal acquisition system
    - Examples: CT, X-ray, ultrasound, MRI images, electrochemical/photometric response from assays, ECG leads, tissue/blood samples, etc.

Criterion 2: Purpose of Software

- The software function must be intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information.
  - Medical information includes **patient-specific information** (e.g., demographics, symptoms, test results, discharge summaries) and **other medical information** (e.g., clinical practice guidelines, peer-reviewed clinical studies, approved drug/device labeling, government agency recommendations).
- To meet criterion 2, the relevance of the information to the clinical decision being made must be well understood and accepted.

Criterion 3: HCP Support

- The software must be intended to support or provide recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition.
- **Exempt CDS enhances, informs, and/or influences a health care decision, but is not intended to replace or direct the HCP's judgment.**
- Software that provides a specific preventive, diagnostic, or treatment output or directive fails Criterion 3.
- Must take into account the level of software automation and the time-critical nature of the HCP's decision making when determining whether the software is substituting, replacing, or directing the HCP's judgement

Criterion 4: Independent Review

- The software function must be intended to enable HCPs to independently review the basis for the recommendations so that they do not primarily rely on such recommendations.
- The software and labeling should include:
  - Purpose/intended use of the product, including intended HCP user and patient population.
  - Identification of required input medical information and instructions on how to obtain it.
  - Plain language description of the underlying algorithm, development, and validation.
  - Software output with relevant patient-specific information.
- Software functions intended for a critical, time-sensitive task or decision do not meet criteria 4 because an HCP is unlikely to have sufficient time to independently review the basis of the recommendations.

Examples of Non-Device CDS Software Functions

- Evidence-based clinician order sets for a particular condition, disease, or clinician preference.
- Matching patient-specific medical information from records or reports to reference information.
- Contextually relevant reference information about a disease or condition.
- Drug-drug interaction and drug-allergy contraindication notifications.
- Drug formulary guidelines.
- Duplicate testing or medication error prevention notifications.
- Reminders for preventative care or clinician's orders.
- Patient data reports and summaries.
- List of preventative, diagnostic, or treatment options.
- Prioritized list of preventative, diagnostic, or treatment options.

Sponsored Projects Office (SPO)

Updates to the Data Use Agreements(DUAs) Process

Agenda

- DUA Process Updates
- New DUA Request Form
- Who Does What?

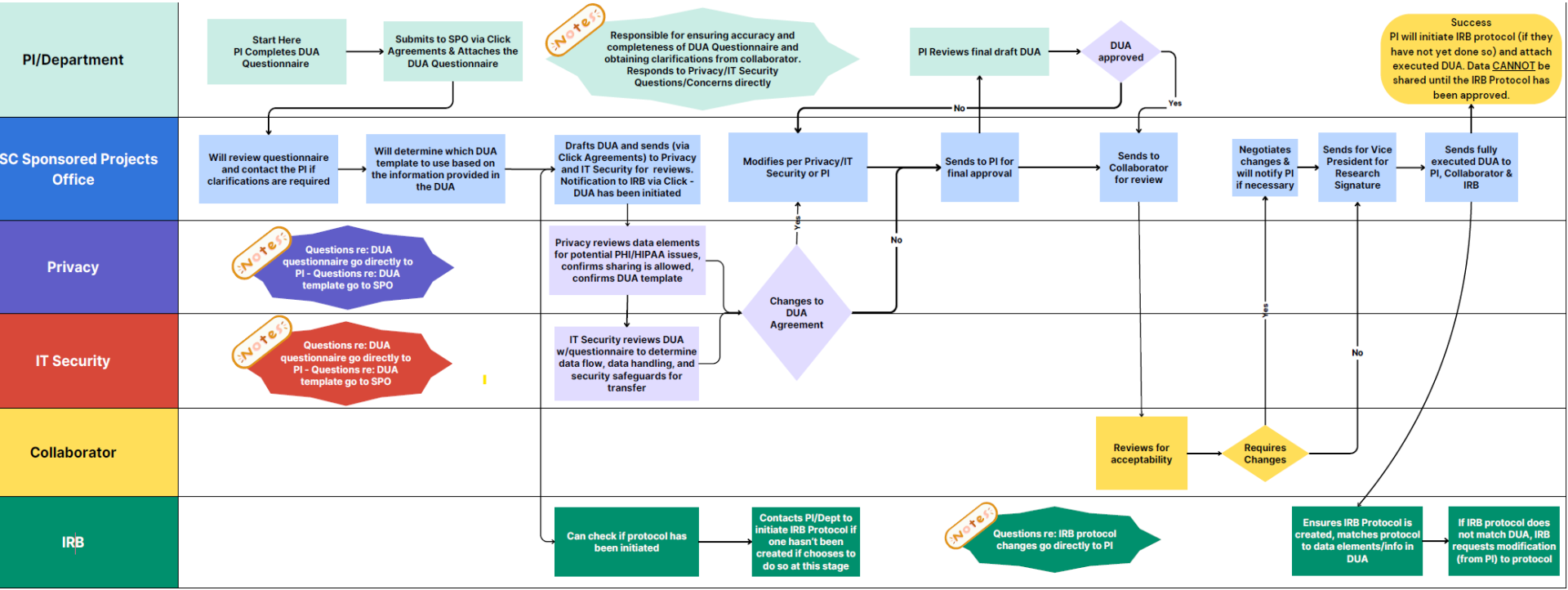
DUA Process Updates

- IRB protocol submission is not required to initiate the DUA process. However, data CANNOT be shared until the IRB protocol has been approved.
- DUAs are now initiated through SPO, with the PI completing the new DUA Request Form and submitting it through the Click Agreements systems.
  - If you are unsure how to create a Click record or don't have a login account, reach out to HSC-PreAward@salud.unm.edu for more information on the appropriate training.
- DUA Workflow is now entirely in Click Agreements.
- Once the DUA is executed, the IRB will be notified. If the IRB protocol does not match, the IRB will work with the PI to modify the protocol.

DUA Process Updates Continued

- All DUAs REQUIRE final approval from our Institutionally Authorized Signatory, the Vice President of Research. Once the agreement is ready for execution, your SPO Specialist will route to accordingly.

DUA Process Flowchart



New DUA Request Form

DATA USE AGREEMENT REQUEST FORM

For all Data Use Agreements (DUAs), please send this completed form, along with any supplementing documents, via Click Agreements (instructions provided) to HSC Sponsored Projects. This form may be used for multiple DUA's under one Project BUT you must provide all collaborator contact information and data elements for each collaborator, however, a separate Click record will need to be initiated for each DUA under this project.

Please note: All information stated in this form must be congruently stated in your IRB protocol if human subject research.

1. Please complete the table below:

HSC Principal Investigator	
Name	
E-mail	
Project title	
Sponsored/ Project Award #:	
HSC PI Proxy	
Name:	
Email/Phone:	
External Party managing the DUA	
Name	
Type	◯ industry/company ◯ academic/research institution ◯ government agency ◯ other ☐ Check here if external party is a

Department contact that can assist with the DUA

Ensure that all questions are thoroughly answered!

Refer to the DUA Request Form Reference Guide for assistance in completing the information.

New DUA Request Form Continued

Collaborator's Sponsored Projects contact information

External Party managing the DUA	
Name	
Type	◯ industry/company ◯ academic/research institution ◯ government agency ◯ other foreign entity ☐ Check here if external party is a
External Party Contact Information Name: E-mail: Phone:	

If there is more than one external party requiring a DUA for this project, please add other external parties. Please include the following for each additional external party:

Organization	Contact Name	Email/Phone	PI Full Name

Include Collaborator's PI information. Use multiple lines for multiple collaborators and complete all information for each.

New DUA Request Form Continued

Provide a summary of the project including how the recipient will use the data.

2. Please provide a short description of the project (limit 250 words)

3. Is the data incoming, outgoing, or will it be shared both ways?

- ◯ Incoming (an external party will be sharing the data with UNM HSC)
- ◯ Outgoing (UNM HSC will share data with an external party)
- ◯ Both/Multidirectional with other institutions

4. Describe how the data will be securely transmitted/shared with another party below:

a. If using a database/data repository managed by another party, please include details about the system such as the URL for the site and the details for who will manage security, maintenance, and access controls for the site. Include institution and contact name.

b. If data is received/sent out using an HSC-managed system**, please choose from the approved list below:**

i. approved list of HSC solutions for data transfer:
   1. HSC's Secure File Transfer System (SFTP)
   2. HSC's REDCap
   3. UNM's Qualtrics (non-clinical data)

ii. if none of the above is an option, describe the plans for receiving, sending out, or accessing data. Consulting with the ISO on options is suggested. Contact ISO at: HSC-ISO@salud.unm.edu. Entering an IT Service request ticket for requesting any of the above services is also available.

The preferred data transfer methods are through HSC SFTP or HSC REDCap. If data is shared via an externally managed web portal, include the website link. For other methods, contact IT Security for assistance: HSC-ISO@salud.unm.edu

For human subject data, provide approved IRB protocol number. The DUA can be negotiated alongside the IRB review, but data transfer requires an approved IRB protocol.

5. Is this human subjects research data? If yes, please provide the IRB protocol number if one exists.

◯ Yes – IRB # _____ ◯ Not applicable ◯ Pending

New DUA Request Form Continued

Indicate the type of data to be shared. Refer to our DUA Request Form Reference Guide or contact the Privacy Office for assistance: HSC-Privacy@salud.unm.edu

6. If this is human subjects data, select which of the following best describes the type of data. Check all that apply. Please see the DUA reference guide for definitions/examples.

- [ ] De-identified human subjects
- [ ] Limited Data Set
- [ ] personally identifiable information (PII)
- [ ] Protected Health Information(PHI)
- [ ] other, please explain

7. If this is human subject data, will the data be **shared with the external parties** include any of the following identifiers? (check all that apply; continue on the next page)

- [ ] Names
- [ ] Any geocodes that identify an individual household such as a street address or Post Office Box Number
- [ ] Telephone number
- [ ] Fax numbers
- [ ] Electronic mail (email) addresses
- [ ] Social Security numbers
- [ ] Health plan beneficiary identifiers
- [ ] Account numbers
- [ ] Certificate/license numbers
- [ ] Vehicle identifiers and serial numbers, including license plate numbers
- [ ] Medical device identifiers and serial numbers
- [ ] Web universal resource locators (URL)
- [ ] Internet Protocol (IP) address numbers

New DUA Request Form Continued

List collaborators along with the data classification and description of the data to be shared.
Example: University X / de-identified / Incoming – Participant #, Vitals, Diagnosis

8. If human subject data, please describe data to be sent out (outgoing) and/or received (incoming) in the table below for each collaborator.

Collaborator (should match listed collaborators in Q1)	Data Classification of the Incoming/Outgoing Data (i.e. limited data set)	Describe Incoming Data	Describe Outgoing Data

9. Is the data that is going to be transferred/shared owned or partially owned by another party? Yes/No

   If Yes, please provide details:

10. Will you also be requiring a Material Transfer Request related to this DUA?

    Yes/No

    If yes, SPO will contact you with further directions.

11. Is the external entity a "covered entity" (HIPAA-covered entities include health care providers (i.e. hospitals, doctors, academic health centers), health plans, and clearinghouses): Yes/No

    Will UNM HSC have an honest broker as part of the data transfer??

    ◯ Yes ◯ No

Note that while a DUA can be executed before IRB approval, an executed MTA requires an approved IRB protocol.

Who Does What?

Sponsored Projects Office (SPO)

- Reviews DUA Request Form to determine DUA template
- Communicates with PI / team to address any questions or concerns
- Drafts and forwards DUA templates to Privacy Office, Information Security Office, and PI for review
- Receives legal dept. approval, if applicable (e.g., template language concerns)
- Negotiates DUA with collaborating institution
- Obtains signatures
- Tracks DUAs in Click ERA

Privacy Office

- Reviews data share information in DUA Request Form (data elements reviewed for potential PHI / HIPAA issues)
- Confirms that proposed sharing of data is allowed under HIPAA Privacy Rule
- Determines / confirms appropriate DUA template, and that data elements are de-identified, limited data set, PHI or other
- Communicates with PI / team to address questions or concerns
- Advises SPO on other privacy standards that apply and language that needs to be included in DUA template
- Receives legal dept. approval, if applicable (e.g., data sharing concerns)

Information Security Office

- Reviews DUA Request Form information to determine data flow, proposed data handling requirements, and security safeguards for storage, transfer and sharing
- Ensures data transfers (sent or received) are secured by HSC Central IT in compliance with all applicable policies and procedures
- Ensures devices that store or share data have been secured in compliance with HSC IT standards
- Communicates with PI / team to address questions or concerns
- Advises SPO with special security needs and recommends modifications to the default DUA template (specific language covering unique security safeguards)

Human Research Protections Office (HRPO)

- Ensures IRB Protocol is created, and that data sharing information aligns with DUA
- If IRB protocol does not match DUA, IRB will work with the PI to modify the protocol

Who to Contact?

HSC Sponsored Projects Office (SPO)

Phone: 272-9383

Email: HSC-PreAward@salud.unm.edu

HSC Privacy Office (Privacy)

Phone: 272-1493

Email: HSC-Privacy@salud.unm.edu

Human Research Protections Office (IRB)

Phone: 272-1129

Email: HRPO@salud.unm.edu

HSC Information Security Office (IT)

Phone: 272-1694

Email: HSC-ISO@salud.unm.edu