DDEAMC Investigator Quick Reference Guide

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I. Process Overview

A. Getting Started:

STEP 1 – Contact the Department of Clinical Investigations (DCI) Research Regulatory Compliance Office (RRCO) for guidance. See Section XI for contact information.

STEP 2 – If the DCI RRCO determines that the project is research involving human subjects or identifiable data, all members of the research team complete the required training (either initial or refresher if it has been three (3) or more years from the initial training).

STEP 3 – Principal Investigator (PI) or designee ensures electronic copies of *Curriculum Vitae (*CVs)/ résumés and certificates of completion for the required training for all research team members are included in the project package. See Section II for guidance.

STEP 4 – Design the research project incorporating the human research subject protections as required by Federal regulations, state law and institutional policies.

STEP 5 – Self-register in IRBNet and review the required "Investigator" documents. See Section IV for guidance.

STEP 6 – Obtain and complete all required documents for submission per the table provided.

STEP 7 - Enter the study into IRBNet for initial review after careful design.

STEP 8 – Receive review feedback and a decision from the Dwight D. Eisenhower Army Medical Center (DDEAMC) Institutional Review Board (IRB).

STEP 9 – Investigator's Responsibilities.

B. Conducting the Research:

Conduct the study in compliance with the IRB approved protocol. Report to the DDEAMC IRB any of the following in accordance with the stated deadlines:

1. Amendments or modifications to the IRB approved research
2. Reportable events to include unanticipated problems involving risks to subjects or others (such as those conducting the research) including serious adverse events or protocol deviations/violations
3. Request continuing review and provide updated information on the conduct of the research

C. Closing/Completing the Research:

Close the project once the research is complete or the PI leaves the institution with no successor. Maintain records and destroy identifiable data in accordance with an IRB approved plan.

II. Required Training

If the DCI RRCO determines that the project is research involving human subjects or identifiable data, all members of the research team complete the required training.

A. Complete the following steps for *initial certification*:

STEP 1 - Register for Human Research Training through the Collaborative Institutional Training Initiative (CITI) at www.citiprogram.org. You must self-register.
NOTE: Select the location as "Dwight D. Eisenhower Army Medical Center". There is an additional facility named Eisenhower Hospital. Please do not select that site. If you do not select the correct site, then the IRB review of the research will be delayed. It takes between 4 and 8 minutes to register for the program.

STEP 2 – Keep your username and password for your records. This will be necessary if you leave DDEAMC and go to another institution that uses CITI as their training program and for the refresher course in three (3) years.

STEP 3 – Select the appropriate "Learner Group" to enroll in the basic course.

STEP 4 – Fully and successfully complete all required modules of the course with a minimal score of 75.

STEP 5 – Print the certificate for your records and scan a copy for your records to upload into your IRBNet User Profile.

STEP 6 – Use the electronic calendar to set up a reminder for your expiration date as noted on the certificate.

B. Complete the following steps for *refresher certification*:

STEP 1 – Login to CITI at www.citiprogram.org using the username and password that you maintained as noted in step 2 for the initial training.

STEP 2 – Select from the "Refresher Courses".

STEP 3 – Fully and successfully complete all required modules of the course with a minimal score of 75.

STEP 4 – Print the certificate for your records and scan a copy for your records to upload into your IRBNet user profile.

STEP 5 – Use the electronic calendar to set up a reminder for your expiration date as noted on the certificate.

III. Protocol Design

A. Identify/contact the research services/resources necessary to safely and efficiently design the project**.**
B. Determine if the project will:
    1. Use existing databases, registries or repositories.
    2. Create new databases from existing clinical data or newly obtained research data, registries or repositories.
C. Determine who will be the research subject.
    1. Determine if the subjects are considered vulnerable according to federal regulations
    2. Determine if the subjects are able to provide informed consent
        a. Children
        b. Incapacitated adults
D. Determine the informed consent process to include:
    1. Initial screening
    2. Recruitment including advertisements
    3. Initial informed consent
    4. Ongoing consent
    5. Withdrawal of informed consent
    6. Applicability of waiver of the informed consent process or documentation of the process as well as the waiver of HIPAA authorization.
E. Address issues of conflict of interest (COI), perceived or real, in the study design. An example may be if the investigator is testing a product that is available only through a relative's company or if the investigator could potentially benefit, financially or personally, through the relationship. Note that the presence of a COI does not negate a project; it simply requires the identification and management of the COI.
F. Address issues of undue influence, perceived or real, in the study design.
G. Description of informing the subjects of the storage of their data or biological sample.
    1. Address issues of the commercial interest(s) for samples as appropriate.
    2. Excess tissue protocols.
    3. Description of the subject's access to genetic information related to their data or biological sample and any secondary use of their sample.
H. Describe the benefits of participating in the research – Determine the advantages to subjects or others for participation in the research.
I. Describe the risks of participating in the research – Determine the types of exposure to the chance of injury or loss to subjects or others such as physical, psychological, financial, social, legal and confidentiality.
J. Address issues of the confidentiality of data and samples.
K. Address issues of the privacy of subjects and invasion of privacy.
L. Address issues of the costs to the subject.
M. Address issues of the significant new findings.
N. Address issues of the withdrawal from research by the subject or the investigators.

Please contact the DCI RRCO staff to set up a pre-research consultation to assist in protocol development if necessary. Contact information is located in Section XI Contact Information.

IV. Types of Research

A. Definitions

1. *Research* (32 Code of Federal Regulations [CFR] 219) means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.
2. *Human subject* (32 CFR 219) means a living individual about whom an investigator (whether professional or student) conducting research obtains:
   a. data through intervention or interaction with the individual, or
   b. identifiable private information.
3. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
4. *Interaction* includes communication or interpersonal contact between investigator and subject.
5. *Private information* includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be **individually identifiable** (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

B. Human versus Non-Human Research

1. Research that may involve humans or human derived materials (medical records, blood or tissues samples, etc.) can be broken down into two types:
   a. Non-human subjects research which is determined by the Human Protections Administrator (HPA) or designee IAW 32 CFR 219.
   b. Human subjects research
      1) Research that does involve human subjects will receive one of the three levels of review as required by the federal regulations:
         a. Exempt from IRB review as meeting the criteria as noted in the DDEAMC HRPP on the DCI website IAW 32 CFR 219.101(b) and 45 CFR 219.110.
         b. Expedited review as meeting the criteria in the DDEAMC HRPP on the DCI website and also at IAW 32 CFR 219.101(b) and 45 CFR 219.110.
         c. Convened board review which has no set criteria other than the proposed project does not meet the criteria outlined for exempt or expedited review.
      2) The levels of review are usually associated with the levels of potential risk which are noted as either:
         a) Greater than minimal risk (GTMR) or
         b) Not greater than minimal risk (NGTMR).

2. Examples and scenarios of research:
   To demonstrate how the determination of whether a research study is human subjects research differs from the determination of whether a human subjects research study is exempt under 32 CFR 219.101(b)(4), consider the following examples, in which an investigator obtains health information of living patients who were treated for arthritis with either Drug A or Drug B. The investigator obtains this information in order to evaluate and compare the treatment outcomes associated with these two drugs:
   a. An investigator obtains only coded information on the treatment outcomes of patients treated for arthritis with Drug A versus Drug B from the patients' treating physician. The only involvement of the treating physician is to provide coded information to the investigator. The investigator and the treating physician enter into an agreement prohibiting the release of the key to decipher the code to the investigator under any circumstances, until the individuals are deceased. In this example, the investigator ***is not*** conducting human subjects research because the investigator cannot readily ascertain the patients' identity. NOTE: The investigator must submit the project for the determination of not conducting human subjects research to the HPA via IRBNet in accordance with the DDEAMC HRPP prior to conducting the project.
   b. An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients' existing individually identifiable medical records at the clinics where the patients were treated. The investigator records the patients' treatment outcomes in a coded manner that could permit the identification of the patients. In this example, the investigator ***is*** conducting human subjects research because the investigator is obtaining identifiable private information from patients' (and now subjects') medical records. The study would not be exempt under 32 CFR 219.101(b) (4) since the investigator is recording the information in a coded manner, thus allowing the subjects to be identified indirectly through identifiers linked to the subjects.
   c. An investigator obtains individually identifiable information on the treatment outcomes of patients treated for arthritis with either Drug A or Drug B by viewing patients' existing individually identifiable medical records at the clinics where the patients were treated. The investigator records only patient age, sex, diagnosis, treatment, and health status at the end of 6 months of treatment so that the investigator cannot link the recorded information back to the patients. In this example, the investigator ***is*** conducting human subjects research because the investigator is obtaining identifiable private information from patients' (and now subjects') medical records. However, the study would be exempt under 32 CFR 219.101(b)(4) since the investigator records the information in such a manner that subjects cannot be identified either directly or indirectly through identifiers linked to the subjects. NOTE: The investigator must submit the project for the determination of exempt from IRB review to the HPA via IRBNet in accordance with the DDEAMC HRPP prior to conducting the project.

C. "Preparatory to Research" provision in the HIPAA regulations

1. There is a method under HIPAA that allows the access of personally identifiable information for the purpose of "reviews preparatory to research."
   a. This method might serve as a part of the:
      1) Design of a research study.

2) Feasibility assessment of conducting a study; or
3) Assembling a database of individuals who indicate a willingness to be considered for participation in future research studies.

b. However, this method does not permit the:
1) Collection of data for conducting actual research; or
2) Removal of information from a covered entity (CE).

2. The researcher must certify to the CE prior to collecting the data, either in writing or verbally, that:

a. The use or disclosure of the protected health information (PHI) is solely to prepare a research protocol or for similar purposes preparatory to research as described earlier.
b. The researcher will not remove any PHI from the CE; and
c. Representation that PHI for which access is sought is necessary for the research purpose in accordance with 45 CFR 164.512(i)(1)(ii).

D. Quality Assurance/Quality Improvement Projects that are Generalizable and Become Research Involving Human Subjects

Quality Assurance (QA)/Quality Improvement (QI) projects are intended to measure and improve performance in the MTF that you are working in but there are instances where the information gained during the QA/QI program should be shared with others that are external to the institution so that changes may be made to other programs. When this instance occurs, the QA/QI project should be submitted to the DCI RRCO for determination of research involving human subjects PRIOR to submitting for publication clearance.

E. Case Studies and Case Series

The reporting on of up to three (3) patients' data obtained from their routine clinical care (the electronic medical record – inpatient or outpatient) as a case series or a single case report does not require a protocol. However the use of four (4) or more patients does require a research protocol. It is important to remember that although these patients may fall under your care for a specific treatment, intervention, etc, the patients and their clinical data are not available to you under research without prospective IRB and privacy board review.

For example, if as a care provider, you notice that a certain drug results in an undocumented adverse effect or side effect and you want to determine if all of the patients at your hospital that have received this drug have the same problem. The data entered into the electronic medical record was for clinical care and already exists so there will not be any additional interaction with the patients. The use of this data that was collected as part of their clinical care for research purposes must be submitted prospectively for IRB review prior to reviewing the data for the question that you have.

An additional example may be that you are concerned about a surgical outcome of early versus late intervention. Again, the data entered into the electronic medical record was for clinical care and already exists so there will not be any additional interaction with the patients. The use of this data that was collected as part of their clinical care for research purposes must be submitted prospectively for IRB review prior to reviewing the data for the question that you have.

F. Interaction Studies

The interaction between a researcher and a research subject may take place in several different scenarios. This interaction could be any of the following:

1. single survey hard copy or electronic or surveys administered at multiple times over the course of the project.
2. focus groups, either single or multiple.
3. research conducted in a clinical environment such as a drug or device trial.
4. simple blood draws.

G. Intervention Studies

Intervention, like interaction, with the subject, may take place in several different scenarios. This intervention could be any of the following:

1. randomization of a research subject diet from low-carb to high-carb to determine weight loss
2. research conducted in a clinical environment such as a randomized drug or device trial
3. assignment of a subject to a different research group

H. Engagement in Research

Determine the engagement of the institution in the research by selecting the location of the project as one or more of the following:

1. Dwight D. Eisenhower Army Medical Center, Fort Gordon, GA
    a. Rodriquez Army Health Clinic, Fort Buchanan, PR
    b. Lawrence Joel Army Health Clinic, Fort McPherson, GA (closing July 2011)
    c. USA Health Clinic, SOUTHCOM, Miami, FL
    d. Camp Shelby, MS
2. Moncrief Army Community Hospital, Fort Jackson, SC
3. Blanchfield Army Community Hospital, Fort Campbell, KY
4. Winn Army Community Hospital, Fort Stewart, GA
5. Martin Army Community Hospital, Fort Benning, GA
6. Lyster Army Health Clinic, Fort Rucker, AL
7. Fox Army Health Clinic, Redstone Arsenal, AL

NOTE: The DDEAMC Institutional Review Board (IRB) is the IRB of record only for the Medical Centers and Health Clinics as noted above and does not serve as the IRB of record for any other organization on the installations noted above.

I. Institutions that are not covered by DDEAMC and its Assurances:

Collaborative research activity exists if the researcher expects "something in return" as a result of having participated in a research activity. Something in return could include data, authorship on a publication, samples, or even patent rights. If, as a result of collaborative research activity, an investigator covered under the Assurances of DDEAMC expects authorship or similar credit, listing an affiliation with the DDEAMC Assurances, such a research arrangement requires DDEAMC IRB review.

J. Other Sites or Interactions

1. National Security Agency (NSA) personnel must submit their protocols to the U.S. Army Medical Research and Materiel Command (USAMRMC) IRB. If a NSA investigator would like to develop a research study that will involve DDEAMC staff, then the investigator should contact the MRMC IRB for additional guidance.
2. If a DDEAMC staff member would like to use data from a DoD database then the investigator should contact PASBA with procedures for requesting access to electronic medical records outside the covered MTF for research purposes.
3. If the researcher is planning to use AHLTA medical records originating outside of the Army, then the PI will need to get authorization from the other DOD branch. Listed below are the Navy and Air Force POCs.

a. Navy

Health Information Manager, Bureau of Medicine and Surgery (M3/5 HCS3)
Building 1, Room 1001, 2300 E Street N, Washington, DC 20372-5000
Phone: 202-762-3162 DSN: 762-3162 FAX: 202-762-3743

b. Air Force

Health Benefits Division, Office of the Surgeon General, AFMOA/SG3SA,
485 Quentin Roosevelt Road, Bldg 171, San Antonio, TX 78226-1865
Phone: 210-925-1185 DSN: 945-1185: FAX: 210-925-1188

V. IRBNet Registration or Changing Affiliations

IRBNet is the electronic web-based system for submission of planned research (human, animal and lab) and publications to the appropriate institutional committees of:

- DDEAMC Institutional Review Board (IRB)
- DDEAMC Institutional Animal Care and Use Committee (IACUC) and
- Publications Clearance Review

As a web-based system, it is available to all research team members with an internet connection to avoid issues such as failure to submit a continuing review request while on TDY, etc.

A. To Self-Register for the DMRN/IRBNet Login, Registration, and Activation in DKO

1. Click on https://www.us.army.mil/suite/page/596540 and login to AKO/DKO using CAC or username and password.
2. Click on the "IRBNet Entry" on the top left (highlighted in yellow).
3. You are at the IRBNet Registration page. You will only see this once. Complete the Registration page.
4. An "activation" email will be sent (usually within 30 minutes) to the email entered in IRBNet:
5. Go to Outlook or your AKO email:
    a. Open the Activation Email and click on the link in the email in order to activate your IRBNet account.
    b. Then click the "IRBNet Entry" link in yellow on upper left side of page.
6. If you are activated in IRBNet, you should see your name in the top left corner under 'Welcome to IRBNet'.
7. You may upload your CV and CITI documentation at this point for future linking to specific protocols.

B. To Change/Add Your Affiliation in DRMN/IRBNet from Your Previous Location to DDEAMC or an MTF Covered by its Assurances:

1. Click on https://www.us.army.mil/suite/page/596540 and login to AKO/DKO using CAC or username and password.
2. Click on the "IRBNet Entry" on the top left (highlighted in yellow).
3. If your account is active in IRBNet, you should see your name in the top left corner under 'Welcome to IRBNet'.
4. Click "USER PROFILE" (on the top right) to update your registration information.
    Please note: If you are, or will be, affiliated with multiple institutional affiliation you can update your User Profile to include those institutions. While on the "USER PROFILE" page, simply click "Add an Additional Affiliation" to associate your name to each institution. This will allow colleagues to quickly find you per your known affiliations in order to share and collaborate.
5. You may upload your CV and CITI documentation at this point for future linking to specific protocols.

C. Additional IRBNet Instructions

1. For additional instructions on the use of IRBNet, refer to the Defense Medical Research Network (DMRN) webpage in AKO. The tabs located on the webpage provide written instructions and guidance for using the IRBNet system:
    a. Guides, Instructions, FAQS for Researchers, Authors, Others Submitting Projects:
        1) DMRN-IRBNet Instructions to Submit Documents for Review
        2) DMRN-IRBNet Help and FAQs
        3) DMRN IRBNet Registration and Activation Guide
        4) Obtaining a DKO-AKO Account
    b. IRBNet Training Videos for Researchers & Committee Members
    c. IRBNet Training for Researchers & Committee Members
        1) Initial Study Submission Training
        2) Subsequent Study Submission Training
        3) How to Submit a Revised Project Package
    d. Links to Member Institutions with their Site Specific Support & Resources
2. Additionally, instructions and training information is located on the DDEAMC IKENet under Clinical Services - Clinical Investigation - Investigator Resources or Education/Training - Research (DCI) - Investigator Resources at https://ikenet.ddeamc.amedd.army.mil/ci/.
3. Tip for using IRBNet – **"Project" versus "Package".**
   Each protocol is a "new" project. Actions taken on a project (such as responding to the initial comments by the IRB, continuing review, amendment, reportable event or closure) are subsequent packages for that project. Each new project receives an IRBNet number that is specific to that project. Each action receives an additional sequential number after the IRBNet number. For example, your new project would be IRBNet #123456-1 where the action of an amendment to this project would be assigned IRBNet #123456-2 and the next action of continuing review would be assigned IRBNet #123456-3.

VI. ***Required Documents***

A. General Documents

1. Listed below is a general list of required documents for a new research protocol submission (IRBNet Project). Documents may be one of three types:
   a. IRBNet Forms and Templates - All forms can be located in the "***Forms and Templates***" area of IRBNet.
   b. IRBNet Document Wizards – There are currently three (3) but DDEAMC is only using two:
      1) DMRN Research Project Cover Sheet
      2) DMRN Publication Clearance Project Cover Sheet
   c. Documents that exist external to IRBNet
      1) Person Specific
         a) CVs /résumés
         b) CITI Certification
      2) Protocol Specific
         a) Protocols submitted to funding sources such as NIH, TATRC, etc.
         b) Sponsor's Protocol and any amendments/addendums
         c) Case Report Forms (CRFs)/Data Collection Tools (DCT)
         d) Advertisements
         e) Recruitment Scripts (phone/internet)
2. Save the documents to a designated folder on your computer and then "upload" into each project (protocol) and/or package (actions taken on a project). It is strongly recommended that a naming convention such as "John.Smith.PTSD Protocol Version Date 4 Nov 10" is used consistently.
3. A description of the document is required when attaching documents in the IRBNet project. The version number and version date (the date that the changes are made) should be specified as part of the description.

B. Determine Required Documents

This section on required documents is organized by the status (package type) of the research:

1. New initial submission for IRB review and approval
2. After the IRB has approved the protocol:
   a. Continuing review at the time period the IRB determined
   b. The protocol is completed and requires closure
   c. Changes are necessary to the protocol/project

For additional assistance please call the Clinical Research Protocol Coordinators at (706) 787-4286/8053 or email EAMC.IRB@amedd.army.mil.

Required Documents for New Initial Submission of a Project for IRB Review and Approval

Document Name	Location in IRBNet	Human Subjects - Expedited or Convened Review-	Human Subjects -Exempt-	Non-Human Subjects Research
DMRN Cover Sheet	*Designer Tab, Add documents, lower part of page*	**X**	**X**	**X**
IRB – Investigator – Form - Protocol Template NOTE: The protocol template should include the request for : • Waiver of the requirement for informed consent - or • Waiver of the documentation of the informed consent process	*Forms and Templates*	**X**	**X**	**X**
IRB – Investigator – Form – Human Consent **OR** IRB – Investigator – Form – Informed Consent, Short Form and Information Sheet, if applicable	*Forms and Templates*	**X**		
IRB – Investigator – Form – HIPAA Authorization **OR** IRB – Investigator – Form – Request for HIPAA Waiver	*Forms and Templates*	**X**	**X**	
IRB – Investigator – Form – Impact Statements, if applicable	*Forms and Templates*	**X**	**X**	**X**
Supporting Documents (Data Collection Sheet/Case Report Forms/Roadmaps, etc.)	*N/A – Developed by the research team and uploaded into IRBNet*	**X**	**X**	**X**

Required Documents for New Initial Submission of a Project for IRB Review and Approval

Document Name	Location in IRBNet	Human Subjects - Expedited or Convened Review-	Human Subjects -Exempt-	Non-Human Subjects Research
Advertisements including Recruitment Materials such as Posters, Radio or TV scripts and Internet or Newspaper ads	*N/A – Developed by the research team and uploaded into IRBNet*	X		

Study Personnel Specific Documents

Document Name	Location in IRBNet	Human Subjects - Expedited or Convened Review-	Human Subjects -Exempt-	Non-Human Subjects Research
IRB – Investigator – Form – PI Responsibilities NOTE: ***Only*** the PI completes this form.	*Forms and Templates*	X		
IRB – Investigator – Form - Conflict of Interest Disclosure NOTE: ***All*** research team members must complete a separate form.	*Forms and Templates*	X	X	X
Curriculum Vitae (CV)/Résumé NOTE: ***All*** research team members must submit a current CV/résumé.	*User Profile*	X	X	X
CITI Training Certificate NOTE: ***All*** research team members must upload a copy of a CITI training certificate to your IRBNet User Profile.	*User Profile*	X	X	
Credentials Required for individuals performing "research related" medical procedures or interventions	*User Profile (if applicable)*	X	X	
Device Training Certification Required for investigational device studies	*NA – Provided by Investigator*	X	X	

Required Documents for New Initial Submission of a Project for IRB Review and Approval

Additional research documents for externally sponsored research such as industry, cooperative group, etc	Location in IRBNet	Human Subjects -Expedited or Convened Review-	Human Subjects -Exempt-
Budget Page (if extramural funding)	*N/A – Developed by the research team and uploaded into IRBNet*	X	X
Cooperative Research and Development Agreement (CRADA)-Statement Work (SOW); if applicable	*Forms and Templates*	X	X
Materials Transfer Agreement (MTA); if applicable	*N/A – Developed by the research team and uploaded into IRBNet*	X	X
Sponsor provided protocol, if applicable	*N/A – Developed by the sponsor and uploaded into IRBNet*	X	X
Sponsor provided template Consent Form, if applicable	*N/A – Developed by the sponsor and uploaded into IRBNet*	X	X
Sponsor provided Case Report Forms (CRFs), if applicable	*N/A – Developed by the sponsor and uploaded into IRBNet*	X	X
Sponsor provided Investigator's Brochure (If IND drug), if applicable	*N/A – Developed by the sponsor and uploaded into IRBNet*	X	X
FDA Form 1572 (If IND drug) , if applicable	*N/A – FDA form - Provided by the sponsor and uploaded into IRBNet*	X	X
Sponsor provided Technical Manual (If IDE device), if applicable	*N/A – Developed by the sponsor and uploaded into IRBNet*	X	X
FDA Investigator Agreement (If IDE device), if applicable	*N/A – FDA form - Provided by the sponsor and uploaded into IRBNet*	X	X

Required Documents for Amendments to Currently Approved Research Studies

Document Name	Location in IRBNet	Human Subjects - Expedited or Convened Review-	Human Subjects -Exempt-	Non-Human Subjects Research
DMRN Cover Sheet (include when cover sheet data changes)	*Project History*	X	X	X
IRB – Investigator – Form – Addendum for Protocol Change	*Forms and Templates*	X	X	X
IRB – Investigator – Form – Human Consent **OR** IRB – Investigator – Form – Informed Consent, Short Form and Information Sheet, if applicable	*Forms and Templates*	X		
IRB – Investigator – Form – HIPAA Authorization **OR** IRB – Investigator – Form – Request for HIPAA Waiver	*Forms and Templates*	X	X	
Revised version of protocol if previously approved documents, are attached	*Project History – select the appropriate version*	X	X	X
Any documents that were previously submitted to and approved by the IRB that require revisions or changes should be submitted (i.e., sponsor's protocol, case report forms, advertisements, etc.)	*Project History – select the previously submitted document and use the pencil icon to update*	X	X	X
Research Team Member Personnel Changes				
IRB – Investigator – Form – Addition of Associate Investigator	*Forms and Templates*	X	X	
IRB – Investigator – Form – Medical Monitor Change	*Forms and Templates*	X		
IRB – Investigator – Form – PI Change Request	*Forms and Templates*	X	X	
Curriculum Vitae (CV)/Résumé	*User Profile*	X	X	X
CITI Training Certificate NOTE: ***All*** research team members must upload a copy of a CITI training certificate to your IRBNet User Profile.	*User Profile*	X	X	

Required Documents for Reportable Events on Currently Approved Research Studies

Document Name	Location in IRBNet	Human Subjects - Expedited or Convened Review-	Human Subjects -Exempt-	Non-Human Subjects Research
IRB – Investigator – Form – Deviation Report, if applicable	*Forms and Templates*	X	X	X
IRB – Investigator – Form – Adverse Event Report, if applicable	*Forms and Templates*	X	X	X

Required Documents for Continuing Review (Applicable Only for Human Subjects Projects that Received Either Expedited or Covened Board Review)

Document Name	Location in IRBNet	Comments
IRB – Investigator – Form – Continuing Review & Closures	*Forms and Templates*	
IRB – Investigator – Form - Conflict of Interest Disclosure NOTE: *All* research team members must complete a separate form.	*Forms and Templates*	Use revision process, if applicable.
IRB – Investigator – Form – Human Consent **OR** IRB – Investigator – Form – Informed Consent, Short Form	*Forms and Templates*	Only necessary if protocol is still enrolling subjects; use revision process, if applicable.
IRB – Investigator – Form – HIPAA Authorization **OR** IRB – Investigator – Form – Request for HIPAA Waiver	*Forms and Templates*	Only necessary if protocol is still enrolling subjects and there are changes to document or document is not in a previous package; use revision process, if applicable.
Curriculum Vitae (CV)/Résumé	*User Profile*	If expired
CITI Training Certificate	*User Profile*	If expired

Required Documents for Requesting Study Closure (Applicable to All Research)

Document Name	Location in IRBNet
IRB – Investigator – Form – Continuing Review & Closures	*Forms and Templates*

VII. Use of IRB Review Agreements (IAIR) between Two Institutions

A. Process for Requesting DDEAMC HRPP to Rely on the IRB at Another Site:

1. Currently, the DDEAMC HRPP can only rely on IRBs at other DoD organizations. Does the other DoD organization IRB of record use IRBNet?
   a. If yes, the primary site project can be shared with the DDEAMC investigator falling under the "share project" (multi-site) tab on IRBNet. This will create a new IRBNet project that the local site investigator will upload site-specific documents into and will be automatically linked to the main site project and its documents. This project should then be submitted to the reviewing IRB and the DDEAMC IRB.
   b. If no, then the project must be created in IRBNet by the DDEAMC investigator and submitted to the DDEAMC IRB for site-specific document review and also sent to the reviewing IRB as directed.
2. Forms Required When Requesting the DDEAMC HRPP to Rely on the IRB at Another Site:

Document Name	Location in IRBNet	Human Subjects - Expedited Category or Convened Review-
DMRN Cover Sheet	*Designer Tab, Add documents, lower part of page*	**X**
Institutional Agreement for Institutional Review Board (IRB) Review (IAIR)	*N/A – Contact DDEAMC DCI RRCO Staff*	**X**
IRB – Investigator – Form - Site Specific Protocol Addendum NOTE: This provides information on how the research team will locally implement the master protocol from the primary site.	*Forms and Templates*	**X**
IRB – Investigator – Form – Human Consent **or** IRB – Investigator – Form – Informed Consent, Short Form and Information Sheet, if applicable NOTE: Required unless the protocol addendum requests waiver of informed consent	*Forms and Templates*	**X**
IRB – Investigator – Form – HIPAA Authorization **Or** IRB – Investigator – Form – Request for HIPAA Waiver	*Forms and Templates*	**X**
IRB - Investigator – Form – Impact Statement	*Forms and Templates*	**X**

Investigator Specific Support Document Name	Location in IRBNet	Human Subjects - Expedited or Convened Review-
Form Name: IRB – Investigator – Form – PI Responsibilities NOTE: *Only* the PI completes this form.	*Forms and Templates*	**X**
Form Name: IRB – Investigator – Form - Conflict of Interest Disclosure NOTE: *All* research team members must complete a separate form.	*Forms and Templates*	**X**
Curriculum Vitae (CV)/Résumé NOTE: *All* research team members must submit a current CV/résumé.	*User Profile*	**X**
CITI Training Certificate NOTE: *All* research team members must submit their CITI certification.	*User Profile*	**X**

B. Process for Requesting HRPP at Another Site to Rely on DDEAMC IRB:

1. Does the other DoD installation IRB of record use IRBNet?
   a. If yes, the DDEAMC site investigator can share the project with other site investigator via the "share project" (multi-site) tab on IRBNet. This will create a new IRBNet project at the other site in which the other site investigator will upload site specific documents. The other site investigator will submit to the DDEAMC IRB for review.
   b. If no, the other site investigator must register in IRBNet. Then, follow the same steps in paragraph B.1.a above.
2. Forms Required When Requesting the HRPP of Another Site to Rely on the DDEAMC IRB:

Document Name	Location in IRBNet	Human Subjects - Expedited Category or Convened Review-
DMRN Cover Sheet	*Designer Tab, Add documents, lower part of page*	**X**
Institutional Agreement for Institutional Review Board (IRB) Review (IAIR)	*N/A – Contact DDEAMC DCI RRCO Staff*	**X**
IRB – Investigator – Form - Site Specific Protocol Addendum NOTE: This provides information on how the research team will locally implement the master protocol from the primary site.	*Forms and Templates*	**X**

IRB – Investigator – Form – Human Consent **or** IRB – Investigator – Form – Informed Consent, Short Form and Information Sheet, if applicable NOTE: Required unless the protocol addendum requests waiver of informed consent.	*Forms and Templates*	**X**
IRB – Investigator – Form – HIPAA Authorization **or** IRB – Investigator – Form – Request for HIPAA Waiver	*Forms and Templates*	**X**
IRB - Investigator – Form – Impact Statement	*Forms and Templates*	**X**
Investigator Specific Support Document Name	**Location in IRBNet**	**Human Subjects - Expedited Category or Convened Review-**
IRB – Investigator – Form – PI Responsibilities NOTE: ***Only*** the PI completes this form.	*Forms and Templates*	**X**
IRB – Investigator – Form - Conflict of Interest Disclosure NOTE: ***All*** research team members must complete a separate form.	*Forms and Templates*	**X**
Curriculum Vitae (CV)/Résumé NOTE: ***All*** research team members must submit a current CV/résumé.	*User Profile*	**X**
CITI Training Certificate NOTE: ***All*** research team members must submit their CITI certification.	*User Profile*	**X**

VIII. Project Preparation and Submission Instructions

A. Required Actions

1. Investigators must submit a new protocol for all research studies involving human subjects (i.e. questionnaires, surveys), collection or study of existing data, documents, records, or specimens. The Principal Investigator (PI) should provide all relevant information via IRBNet. Upload all applicable documents from Required Documents (see Section VI) of this guide.
2. Share project package with PI, AI, MM, Service or Dept Chief (read only access) for non-investigators and those investigators who will not be communicating directly with the IRB
3. Individuals named as the PI, AI, MM, Dept Chief or Higher click on "***Sign this Package."***
4. After obtaining all electronic signatures, PI will "***Submit this Package"*** to the appropriate IRB***.*** Note: Submit each package only once. If a package was submitted previously, and unlocked for changes/editing then you must "Mark-Revisions Complete" which will in turn lock the package and notify the DCI RRCO you have completed your changes.
5. The Investigator must promptly reply to all requests for revisions and/or clarifications requested by the designated reviewers, when applicable. Requested revisions, changes or additions to the protocol package in IRBNet will generally be accomplished ***after the DCI RRCO staff "unlocks" the protocol package***. Upon completion of the designated reviewers requested actions, the investigator must only select the ***"Mark Revisions Complete***" in "***Designer"*** section of the package and will **not** submit the package to the DDEAMC IRB. Only newly created packages (new protocols) are submitted to the IRB. Packages "***unlocked***" for editing are not to be submitted again.

B. Training

There are training materials (videos, etc.) on the DMRN website and the DCI RRCO staff is available for guidance.

IX. Document Descriptions/Examples

Conflict of Interest/Financial Disclosure
This form must be completed by all research team members for each protocol. It primarily refers to the financial interest but may be used to report other conflicts, as necessary.

DMRN (Defense Medical Research Network)Cover Sheet
This cover sheet is attached to each specific project. It requires an update each time that the data fields contained on the cover sheet change. It is used primarily as a reporting tool to the Office of The Surgeon General.

Impact Statements
Impact Statements are to be completed by all departments that are impacted by the conduct of this research to ensure that they are:

- Aware of the research being conducted in their area
- Cognizant of their responsibilities for supporting this research to include financial, space and personnel (including nursing staff) support

The impact statement documents the department's support for the research.

HIPAA Authorization
An authorization is a detailed document that gives covered entities permission to use protected health information for specified purposes, which are generally other than treatment, payment, or health care operations, or to disclose protected health information to a third party specified by the individual.

An authorization must specify a number of elements, including a description of the protected health information to be used and disclosed, the person authorized to make the use or disclosure, the person to whom the covered entity may make the disclosure, an expiration date, and, in some cases, the purpose for which the information may be used or disclosed. With limited exceptions, covered entities may not condition treatment or coverage on the individual providing an authorization.

Institutional Agreement for IRB Review (IAIR)
An IRB authorization agreement that allows an institution's human research protection program (HRPP) to rely on the IRB of another institution.

Protocol
A plan to conduct the research, and includes any addendums/attachments such as the sponsor protocol, Consent Form, Case Report Forms (CRFs), Investigator's Brochure, and FDA Form 1572 (if IND drug).

Research Informed Consent Form
We use a DA form that documents the requirements and documents the voluntary participation of subjects in the research informed consent process. It should be for all individuals who may be research subjects – adults, spouses, parents, children, etc.

Site-Specific Protocol Addendum
A form that provides information to the host institution's HRPP about the local implementation of a protocol approved by the IRB of record on the IAIR.

Supporting Documents - (Data Collection Sheet, Recruitment Materials/Poster, etc)

These are the documents that are not outlined separately in this section. It includes data collection sheets (such as an Excel spreadsheet), recruitment materials (telephone recruiting scripts, posters, etc.), and other documents.

X. Responding to the IRB

A. IRB Feedback

The IRB will provide feedback to the investigator via IRBNet Project Mail. The feedback may require changes or clarification in order to provide information so that the IRB can determine the approvability of the protocol.

Each action item submitted via IRBNet will involve two levels of review:
1. Administrative review by the DCI RRCO staff and
2. IRB Member or Convened Board Review

B. Investigator Responses

The responses to the DCI RRCO staff or the IRB should be submitted in the following formats to ensure that the information can be reviewed as quickly as possible and to avoid any further delays:
1. Use the track changes feature on all Word documents so that changes are noted and version control is assured. This includes changes to the protocol, informed consent documents, etc.
2. A cover memo is required for all responses. This memo format should include copying and pasting the IRB required changes and then the PI response. Each change must be responded to so that the project may move forward.

   NOTE: The PI may choose not to make the change requested, and justification must be provided. This justification may be based on such factors as the PI experience with the primary study population or new literature.

   Example:

   IRB Requirement:

   > Revise the protocol to exclude women of childbearing potential.

   PI Response:

   > The protocol was revised to exclude women of childbearing potential as noted on page four, section three and the revised statement in the protocol now reads: Women of childbearing potential are excluded.

XI. Contact Information

DDEAMC IRB "one-stop" email address is EAMC.IRB@amedd.army.mil

CITI program (required education) is available at www.citiprogram.org and is available from any internet connection.

IRBNet self-registration is required and is available through the AKO/ DMRN page: https://www.us.army.mil/suite/page/596540

Role	Necessity	Point of Contact (POC)
Librarian	Conduct the literature search for similar research	DDEAMC Librarian 706-787-6765
Statistician	Determine the minimum of subjects/samples necessary to conduct the project	DDEAMC Contracted Statistician 706-667-4616
Pharmacy	Necessary for protocols that will use investigational new drugs or devices All of the medications are stored there along with the protocols and she is the pharmacy rep on the IRB.	Oncology Pharmacist 706-787-1127
DCI RRCO/IRB Support	Subject matter experts on IRBNet, research design, human research protection issues, etc.	EAMC.IRB@amedd.army.mil Research Protocol Coordinators: 706-787-4286 706-787-8053 Research Compliance & IRBNet Administrator: 706-787-7165 Human Research Protections and Compliance Administrator: 706-787-2387

XII. Publication Clearance

A. Proper clearance must be obtained *before* the publication is submitted

The author/presenter must obtain review and approval of the document/presentation (journal, book, meeting, etc.) ***before*** a scientific abstract or manuscript is submitted for publication or presentation. The individual must also obtain official clearance for the publication/presentation ***before*** a scientific abstract or manuscript is submitted for publication or presentation.

Review of the planned publication or presentation is necessary to ensure defense security requirements including the provisions of AR 530-1, and The Army Public Affairs Program, are satisfied. The information must be submitted via IRBNet to the Publication Clearance board.

Refer to Chapter 16 Dissemination of Research Findings in the DDEAMC HRPP for additional information.

B. Requirements for DDEAMC approval for Publication Clearance

The following publications and abstracts require DDEAMC approval:

1. Reports citing a MTF covered under DDEAMC Assurances in the title or byline;
2. Reports of DDEAMC approved research projects;
3. Reports of research performed by staff (military, civilian or contractor) assigned to an MTF covered under DDEAMC Assurances.

C. Process for Publication Clearance Submission

All requests for Publication Clearance are submitted via IRBNet to the DDEAMC Publication Clearance, not the DDEAMC IACUC or DDEAMC IRB.

1. Publication material not a result of a DDEAMC IRB approved protocol – Create a new IRBNet Project. The Publication Clearance Project Cover Sheet is completed using the Document Wizard. Click on "Add New Document" under Step 2. Use the drop down box arrow next to "On-Line Documents" to select the Pub Clearance Cover Sheet document wizard and follow the prompts.
2. Publication material is a result of a DDEAMC IRB approved protocol - Do not create a new IRBNet project. Open the research project in IRBNet that is associated with the submitted publication materials and create a subsequent package to that project and submit it to DDEAMC Publication Clearance. A copy of the protocol is already in the project and does not need to be added again.

D. Author Responsibilities

1. Confirm that all publications and presentations of DDEAMC human subjects' research results contain the following statements, as applicable:
   a. Approved for public release; distribution is unlimited.
   b. The investigators have adhered to the policies for protection of human participants as prescribed in Army Regulation 70-25, and the research was conducted in adherence with the provisions of 32 CFR Part 219.
   c. Disclaimer Statements: The opinions or assertions contained herein are the private views of the author(s) and are not to be construed as official or reflecting the views of the Army or the Department of Defense.

2. The following statement must be included if specific brand names or commercial products were utilized during the study:

   Any citations of commercial organizations and trade names in this report do not constitute an official Department of the Army (DA) endorsement of approval of the products or services of these organizations.

3. All written materials, including manuscripts, abstracts, and book chapters reflecting the DDEAMC or one of its covered MTFs under the Assurances, must be cleared through the DDEAMC Commander and Public Affairs Officer (PAO) and the Security Officer (SO).
4. Publications that describe traumatic brain injury or post-traumatic stress disorder must receive an additional level of review from The Surgeon General's Office.