PURPOSE

The purpose of this SOP is to provide standard operating procedures for how Office of Protocol Review and Reporting activation coordinators should complete the activation processes for research protocols (clinical, PBHSR and protocol applications).

SCOPE

The activation process serves to ensure that, before any study is opened for patient enrollment, a thorough review of relevant regulatory, financial, and clinical criteria has been performed and documented. This mechanism enhances the safety of potential participants and helps to ensure that studies opened at MD Anderson are compliant with institutional and federal guidelines.

PROCEDURE

ACTIVATING RESEARCH PROTOCOLS

A protocol must be approved by either the MD Anderson Institutional Review Board (IRB) or, in the case of certain applicable trials, by an outside IRB before the activation process can begin.

Activation Request

- An Activation Request must be created by the Principal Investigator’s office and sent to the IRB office via PDOL or via email and sent to IRB Help or OPR Protocol Activations. Investigators are encouraged to utilize the PDOL Activation Memo so that desired designations for protocol set up are easily outlined according to their responses to the questions on the memo. The information provided in the Activation Request Memo will determine how the information (eligibility, strata, regimen) is set up in admin CORE.
Subject: Request for Activation - 2010-0736

Please activate this study.

- Would you like eligibility set up in steps?
  Yes
  Designate which eligibility will be answered at registration
  5. Patients must be willing and able to review, understand, and provide written consent before starting therapy.

- If the protocol contains multiple treatment regimens, would you like this information entered in CPOe?
  No

- If the protocol contains steps, would you like this information entered in CPOe?
  No

Please contact ORR at 713-792-2123 or send an email to IRB_Help@mdanderson.org to discuss protocol setup preferences in CPOe.

Vicky H. Zeller 01/03/2011 10:12:17 AM
IRB Approval

- The activations coordinator will confirm that the protocol has been IRB approved by accessing PDOL, or the CORe or PDMS databases.
- In case of use of an outside IRB, there will not be an IRB approval date in CORe. Study team will provide a copy of the outside IRB approval memo and for CIRB oversight – the Study Specific Worksheet, before the activation process can begin.

Accessing PDMS

1. Enter Login information
2. Type in “Stat” for Status Screen
3. Type in protocol number
4. Review information in the IRB meeting date field (and IRB contingencies met date field, if applicable) to confirm IRB approval status.
Accessing Admin CORe

1. Enter Login Information
2. Select Protocol Status
3. Type in protocol number
4. Review information in the IRB Approval Date field to confirm IRB approval status.

Activation Comments

- Confirm in Clinical Oncology Research (admin CORe), select Protocol Status to view the Activation Comment and Administrative Note fields. You may also want to review the initial IRB memo in PDOL.

- If there is an activation comment, make sure the required action has been completed. For example, if the activation comment calls for a future amendment that has not been submitted, send an email to the PI and the PI staff included in the activation request memo and let them know what amendment needs to be submitted and IRB approved before the activation process can proceed. (This may involve you reviewing resubmission memo(s), the initial IRB approval memo, as well as the Clinical Research Committee (CRC) reviewer memos. [These memos will be in the early versions of the protocol and will be indicated as reviewer comments].)
Clinical Research Finance

- **In admin COREs, select Protocol Setup, click CR Fin tab.**
  - If Patient Care Coverage Analysis field is set to: yes, signed OR exempt – CRF Requirements Met – AND -
  - If Patient Care Contract/Grant field is set to: approved OR not applicable – CRF Requirements Met – AND -

- If any of these fields state: Pick me, Sent to PI, In Review, or In Process - Do Not Proceed with Activation – CRF Requirements are Not Met.
  - Send an email to the PI, PI staff included in the activation request memo, and copy Clinical Research Finance (CRF). In the email instruct the PI and staff to contact CRF and let them know which fields need to be updated by CRF. Include in the email that the activation process cannot proceed until these fields have been updated by CRF.
Patient Remuneration

✓ Confirm in the informed consent if patient remuneration is available.
✓ For studies submitted in PDOL after 10/01/2016, email CRF-ParticipantRemuneration <CRF-ParticipantRemuneration@mdanderson.org> to confirm bank card is ready.
Study Agent(s)

- Review the informed consent/abstract/protocol to determine if study agent(s) is being provided.
  - If yes, contact the Investigational Pharmacy via email to Investigation Drugs or call 713-792-2848 to confirm that study agent(s) has arrived and Investigational Pharmacy is ready for the study to be activated.
  - If the study agent(s) has not yet arrived, send an email to the PI, PI staff included in the activation request memo, and copy Investigational Drugs asking if the Study Sponsor has any specific requirements regarding agent supply (e.g., some sponsors will not ship the study agent until a potential subject has been identified). If the PI is asking for activation before provided study agent(s) has arrived, Investigational Pharmacy must be made aware and agree to this.
### Investigational Device (IDE)
Does this study utilize an Investigational Device? N/A

### Sponsorship and Support Information
Does the Study Have a Sponsor, Supporter or Granting Agency? Yes
Sponsor Name: [Name]
Support Type: [Type]
Agent Name(s): [Agent]
This Sponsor/Sponsor/Granting Agency will receive data.

### Regulatory Requirements

<table>
<thead>
<tr>
<th>Regulatory Category</th>
<th>Description</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Radioactive Material</td>
<td>Administration of radioisotopes or a radiolabeled agent?</td>
<td>N/A</td>
</tr>
<tr>
<td>Biosafety</td>
<td>Does this study involve the use of Recombinant DNA Technology?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Does this study involve the use of organisms that are infectious to humans?</td>
<td>No</td>
</tr>
<tr>
<td></td>
<td>Does this study involve human/animal tissue other than blood derived hematopoietic stem cells?</td>
<td>No</td>
</tr>
</tbody>
</table>

Questions should be addressed to the Transfusion Medicine Tissue Coordinator at 713-792-8530.

### Laboratory Tests:
Is there any biomarker testing in this study being used to determine patient/participant eligibility, treatment assignment, or management of patient/participant care?  
- Yes
- No
- Not Applicable For This Protocol

### Manufacturing:
Will you manufacture in full or in part (split manufacturing) a drug or biological? No
**Investigational New Drug (IND)**

- Check in the abstract, protocol, and/or PDMS (protocol status) [for MDACC IND] to see if the study is being conducted under an IND.
• An MDACC IND study should have the initials FDA outside the protocol in the Protocol Document On Line system (PDOL).

➢ For an MDACC IND study, email the IND Office to confirm their requirements have been met. Do not enter the MDACC IND information in CORE.

➢ If the IND Office requirements have not been met, send an email to the PI, PI staff included in the activation request memo, and copy the IND office and tell the PI and staff to contact Stella and/or Eliana for additional information. Include in the email that the activation process cannot continue until the IND Office requirements have been met.

➢ If the study is being conducted under a Sponsor IND, in admin CORE, Protocol Status, enter: the IND number, the category IND, and the Source Risk.

➢ If the study is not being conducted under an IND, in admin CORE, Protocol Status, enter: either n/a or exempt (determined from the information in the abstract and/or IND group), the category IND, and the Source Risk
**Investigational Device Exemption (IDE)**

- Check in the abstract, protocol, and/or informed consent to see if an investigational device is being used. (You may need to look up on www.FDA.gov and/or review the IRB minutes/initial approval memo)
- Check in the abstract and protocol, to see if the study is being conducted under an IDE.
  - If the study is being conducted under an IDE, in admin CORe enter: the IDE number, the category IDE significant risk, and the Source Risk.
  - If the study is not being conducted under an IDE, in admin CORe enter: either n/a or exempt (determined from the information in the abstract, IND Group, and/or IRB initial approval memo), the category non-significant device, and the Source Risk.
MDACC Tissue Banking

✓ Check in the Informed Consent to see if the study is utilizing a MDACC tissue bank. If the study received initial IRB approval after 11/01/2010, login into Tissue Station http://TissueStation.mdanderson.edu to confirm protocol registration in Tissue Station requirements is complete, before the study is activated. Enter banking information into CORE.
Admin CORe
1. Click on Protocol Status Folder, type protocol number, enter
2. Click on Biospecimen/Data tab
3. Answer questions based on information in protocol.
4. Under Banking Comment – type in summary of what is being banked.
Community Program (CCOP) Study
✓ Check in the abstract (where will this study be conducted section) to see if the study is a CCOP study. If a CCOP study, call the CCOP Research Base Staff at 713-563-0276, to confirm their requirements have been met. If the CCOP group requirements have not been met, send an email to the PI, PI staff included in the activation request memo and tell the PI and staff to contact the CCOP Research Base Staff for additional information. Include in the email that the activation process cannot continue until the CCOP group requirements have been met.
NCI Study

- Check in the abstract, protocol, and/or informed consent to determine if the study is an NCI CTEP or DCP study.
- If the study is NCI, NCI group to confirm their requirements have been met. If the NCI group requirements have not been met, send an email to the PI, PI staff included in the activation request memo, and tell the PI and staff to contact the NCI group for additional information. Include in the email that the activation process cannot continue until the NCI group requirements have been met.
- An NCI study, where MDACC is the lead site, should have the initials NCI outside the protocol in (PDOL).
Outside MD Anderson IRB Oversight

- Check in the abstract, protocol, informed consent and/or previous IRB memos to determine if the study is being conducted under an external IRB Oversight
  - If the study being done under CIRB oversight, email (Navira Khan) to confirm their requirements have been met. If the NCI group requirements have not been met, send an email to the PI, PI staff included in the activation request memo, and copy Navira Khan and tell the PI and staff to contact the Office of Human Subjects Protection for additional information. A study, being done under CIRB oversight should have the initials CIRB outside the protocol in (PDOL).
  - Currently for external IRB, there is also Western IRB (WIRB) and Quorum IRB.
**Documenting External IRB Oversight**

**Admin CORE**

1. Click on Protocol Status Folder, type protocol number, enter
2. Click on Engagement tab
3. Answer questions based on information in protocol.
Injury language

✓ Check **STUDY COSTS AND COMPENSATION** section in the informed consent. If there is mention of the sponsor paying for costs associated with an injury, copy the section and email scientific editors, Dave Mitchell and Kristofer Griffin for their review and comments. If Dave/Kristofer indicate the language in not acceptable, send an email to the PI, PI staff included in the activation request memo, and copy Kristofer Griffin and tell the PI staff to contact the scientific editors for additional information. Include in the email that the activation process cannot continue until the language is approved.

✓ There may be a memo from the Sponsor regarding payment for injury included as an Appendix in PDOL.
LBJ Site

✓ Check in the abstract under the Study Enrollment and Accrual sections. If any Harris Health System [previously known as, Harris County Hospital District (most common site is LBJ)] is listed, to confirm their requirements have been met prior to activating the study.
CLIA

- Check in the abstract under Laboratory Tests.
  - If "not applicable for this protocol" is selected, you do not need to do anything additional.
  - If "no" is selected, you do not need to do anything additional.
  - If "yes" is selected, you will need to look in the earlier versions of PDOL under Reviewer Memos or in the "blue" packet under the Misc. tab in the protocol folder for CLIA resolution done during the CRC process. If CLIA resolution not completed during the CRC process you will need to send an email to Ann Reynolds asking to review, to determine if CLIA certificates are needed for the "other" labs. You can also email the PI and PI staff included in the activation request for the CLIA certificates for the "other" labs. Include in the email that the activation process cannot continue until the CLIA issue has been resolved. If no response is received, please discuss with Wanda Quezada.
Radiation Safety
- Check in the abstract under Radioactive Material. If marked yes, contact EH& S, Sandra Jimenez at 713-563-9339 or Billie Harvey at 713-563-3747. You may also look in the protocol folder under Misc tab for The Radiation Safety Committee approval memo. If “no” is selected, you do not need to do anything additional.

Biosafety
- Check in the abstract under Biosafety. If any of the questions are marked yes, contact the Institutional Biosafety Committee (IBC) Mainline at 713-563-3879. You may also look in the protocol folder under Misc tab for IBC approval memo. If “no” is selected, you do not need to do anything additional.

Manufacturing
- Check in the abstract under Manufacturing.
  - If “no” is selected, you do not need to do anything additional.
  - If marked yes, contact Suzanne Dworsky via email for review.
  - Note Investigational Pharmacy may also indicate if GMP facility at UTMDACC is involved. This will also require an email to Suzanne Dworsky for review.
  - On newer studies 2012 and higher, check in the protocol checklist appendix, under use of MD Anderson Cell Therapy Lab GMP facility. If marked yes, contact Suzanne Dworsky via email for review.
### Type of Funding:
- [ ] NCI
- [x] NIH (other than NCI)
- [ ] DOD
- [ ] Other peer reviewed funding (e.g. NSF or ACS etc.)
- [x] Industry
- [ ] Departmental Funds
- [ ] Donor Funds
- [ ] Unfunded
- [ ] Not known at this time
- [ ] Other

### Source of Agent/Device:
- [ ] NCI
- [ ] NIH (other than NCI)
- [x] DOD
- [ ] Industry
- [ ] Departmental Funds
- [ ] Commercially available
- [ ] Not known at this time
- [x] Other

List any device(s) which will be used (if applicable):

**Use of the CTRC**

Will the Clinical and Translational Research Center (CTRC) be used in this study?
- [ ] Yes
- [x] No

**Use of the MD Anderson Cell Therapy Lab GMP facility**

Will the protocol require the services of the Cell Therapy Lab Good Manufacturing Practice (GMP) facility or products to be manufactured using the GMP facility?
- [ ] Yes
- [x] No

**Laboratory Data**

Will a UTMDACC investigator perform pharmacologic, molecular or other laboratory studies on patient specimens?
- [ ] Yes
- [x] No
OneConnect

- Check in the CORe to see if the study is financially exempt or not.

- If “YES” is selected, you do not need to do anything additional.

- If the study is not financially exempt and the In EPIC note is there, you will need to confirm the CRF Billing Note has been entered in OneConnect.

This document is the property of The University of Texas MD Anderson Cancer Center and, with few exceptions, may not be used, distributed, or reproduced outside of MD Anderson without written permission from the Office of Protocol Review & Reporting. (Version 1.3, last edited 11/2018)
If the CRF Billing Note has been entered in OneConnect you do not need to do anything additional.

If the CRF Billing Note is not entered in OneConnect, you will need to go to Cherwell and find the ticket associated with the study and create a task for EHR Clinical Research Finance, for them to enter the CRF billing note when appropriate.

Once the CRF Billing Note has been entered in OneConnect and all other activation requirements have been met, you will enter the automated actions and change the status to Active.

Once the study is activated, you will go in Cherwell and resolve the ticket.
Sponsor/Supporter

- Check in the abstract and protocol checklist abstract to confirm sponsor/supporter information.

- If Sponsorship and Support Information in the abstract indicates "none", and the Type of Funding in the protocol checklist indicates "unfunded" send an email to the PI, PI staff included in the activation request memo, asking for further details. Contact Wanda Quezada to discuss.

- If Sponsorship and Support information in the abstract indicates DoD (Department of Defense) verify DoD human subjects approval through HRPO. Contact Wanda Quezada to discuss.
Financial Support and Use of the CTRC

How is the proposed study to be financially supported?

Type of Funding:
- NCI
- NIH (other than NCI)
- DoD
- Other peer reviewed funding (e.g. NSF or ACS etc.)
- Industry
- Departmental Funds
- Donor Funds
- Unfunded
- Not known at this time
- Other

Source of Agent/Device:
- NCI
- NIH (other than NCI)
- DoD
- Industry
- Departmental Funds
- Commercially available
- Not known at this time
- Other

List any device(s) which will be used (if applicable): N/A

Use of the CTRC

Will the Clinical and Translational Research Center (CTRC) be used in this study?
- Yes
- No

Use of the MD Anderson Cell Therapy Lab GMP facility

Will the protocol require the services of the Cell Therapy Lab Good Manufacturing Practice (GMP) facility or products to be manufactured using the GMP facility?
- Yes
- No
GRC Risk Assessment

- Confirm in Clinical Oncology Research (admin CORe), select Protocol Status to view the Activation Comment and Administrative Note fields. You may also want to review the initial IRB memo in PDOL.
- Activation Comment will indicate to confirm database or other electronic method has been vetted by MD Anderson and to check with Information Security.
- Ask study team if they have documentation from Information Security regarding signoff. If not, Create a ticket in Cherwell and assign to Information Security (Infosec) Cherwell team ISD-Risk Advisory.
  - Activation cannot proceed until risk assessment received from Information Security.
Outside Treatment

- Check in the informed consent to determine if it contains Outside Treatment section.

If there is an Outside Treatment Section in the informed consent, check the appendices for a “Dear Doctor” letter. Review previous IRB Memos in PDOL to determine if an “engagement in research” determination has been made. If not, send an email to the IRB Chair/Designee asking for review of the outside treatment issue. IRB Approval is needed. If not IRB approved, send an email to the PI, PI staff included in the activation request memo letting them know the Outside Treatment is not IRB approved, and a revision removing the statement must be submitted and IRB approved before activation can proceed.
UTMDACC Lead Site

Check in the abstract, under Study Enrollment, to see if MDACC is the lead site in a multi-site study.

- If "no" is selected, you do not need to do anything additional.
- If the study a multicenter, investigator initiated, grant funded study (no pharmaceutical company oversight/CRO), or if this study an IND exempt and multicenter study where MD Anderson is the lead site, need to confirm a protocol monitoring plan is included in the protocol. Send an email to the CRSC-IRB Review to review the protocol and possibly provide monitoring for the outside sites. Contact Wanda Quezada to determine if an Authorization Agreement will be needed.
Title Check
✓ Confirm protocol title is the same in PDOL, admin CORe, and PDMS protocol status.

Signatures
✓ Confirm signatures are complete for all Co-Investigators and Collaborators. Electronic signatures in PDOL, hard copy signatures in the protocol folder.

Eligibility
✓ Enter the eligibility in admin CORe, according to the setup preference listed in the activation request memo

Investigational Brochure
✓ Check in the appendices to determine if an Investigational Brochure for the agent being used is attached.

CORE and PDMS Database Updates
✓ Check in the protocol to see if the protocol has a sponsor protocol number listed. If yes, enter the sponsor protocol number information in CORe, Protocol Set-Up.
✓ Check in the abstract under Treatment Agents/Devices/Interventions. Enter information in PDMS, core protocol information.
✓ Check in the abstract under Disease Group. Enter information in admin CORe, Protocol Set-Up, CCGS tab, Protocol Site
✓ Enter protocol category into admin CORe, Protocol Set-Up
✓ Enter protocol type into admin CORe, Protocol Set-Up
✓ Enter phase designation into admin CORe, Protocol Set-Up
✓ Confirm the total accrual at UTMDACC in the abstract and informed consent. Enter this number as the maximum accrual number in admin CORe, Protocol Status. Check the UTMDACC abstract to see if this is a multi-center protocol, if yes, enter the total accrual number as the multicenter total in admin CORe, Protocol Status.
✓ Count the number of UTMDACC IRB approved informed consents. Enter consents per protocol into PDMS, core protocol information.
Activation Date/Informed Consent IRB approval Date
✓ Confirm that there is a UTMDACC IRB approved informed consent.
   Enter the date you activate the protocol as the first consent approval date in admin CORE, Protocol Status, Informed Consent.
   Check the protocol to see if there is also a waiver of informed consent/authorization.
   If yes, check the consent form waiver box in admin CORE, Protocol Status.
   (There may be times when there is both a consent and a waiver, this is okay).
   If the study is utilizing the questionnaire statement, please state this in an admin note in admin CORE, Protocol Status.
✓ Enter the date you activate the protocol as the activation date in admin CORE, Protocol Status.
✓ Change the status of the current IRB approved protocol in PDOL to activated, and change the status change date to the date you activated the protocol. Enter the consent approval date as the date you activated the protocol.

Activation Memo
✓ In PDOL, Compose IRB Memos, Activation memo. Click the appropriate boxes if the protocol sponsor is FDA or NCI. Send the activation memo to the PI, and the PI staff included in the activation request memo, and Evanna Thompson. If the protocol is utilizing a provided study agent also copy Investigational Drugs.

Filing
✓ Print out electronically signed protocol documents and IRB approved stamped informed consent and file in protocol folder.

PA
✓ Please see procedures for activating various types of Protocol Application.
ACTIVATING NEW PROTOCOL APPLICATIONS

Before activating any study, ensure that all signatures have been obtained and required CRF fields are updated.

1. Check CRF fields in Admin CORE (under Protocol Setup): Oncology Administration/Entry/Protocols/Protocol Setup

1. Enter Protocol #
2. Click on CRF tab (3rd tab)
3. Make sure all fields below are updated:
   1. Patient Care Coverage Analysis: EXEMPT
   2. Patient Care Contract/Grant: NOT APPLICABLE
   3. Research Ticket: NOT APPLICABLE
   4. PI Signature Date of Coverage Analysis: DATE
   5. CMS Qualified: NO

2. To activate in Admin CORE (under Protocol Status):

   - IRB Approval Date: Date chair approved protocol on Expedited Review form
   - Activation Date: today’s date
   - Enter max accrual # for site and multi-center sites if applicable (enter 0 in multi-ctr if only at MDA)
   - Check boxes for:
     1. Waivers? If so, check box
     2. Registration Required? Check if study has Waiver & 51 or more subjects
        - NOTE: If IC, do not check any boxes
     3. If Waivers and 51 or more subj, check all 3 boxes

   - Informed Consent Tab: Consent Approval Date: same as Activation Date
   - If there is an IC or less than 51 subjects, go to Eligibility entry
     a. Enter Inclusion criteria – check yes
     b. Enter Exclusion criteria – check no
     - Check Eligibility Ready box, save and close

3. To activate in PDOL:

   G
   o into version sent to IRB chair
   - Protocol Staff/Edit section
     - Mission Status: change Activated
   - Consent Approval Date (if ICD): Today’s date
   - Compose
     - o IRB Memo: New Protocol PA
     - o CC Wanda, Marion and Yadira
     - o IRB Home Assignment: Select 4 M T A t i i M
4. To activate in Web CORE:
   1. DATABASE
   2. ENTER PROTOCOL #, then PROT. SEARCH
   3. DATA ENTRY TAB
   4. UNDER REGULATORY ACTIONS, ACTIVATION DOCUMENTATION
   5. ACTIVATION INITIATION DATE: today’s date
   6. COVERAGE ANALYSIS COMPLETE: today’s date
   7. CONTRACT/GRANT COMPLETE: today’s date
   8. RESEARCH TICKET COMPLETE: today’s date
   9. All other fields: check n/a box.
      -If ICD, enter today’s date in ICD EDITOR CHECK COMPLETE
      -If ICD translation is required, enter today’s date in ICD TRANSLATION COMPLETE

UNDER ACTIVATION CHECKLIST:

-Check all boxes if 50 or less subjects. If 51 or more, do not check
ELIGIBILITY CHECK IN CORE box
-ACTIVATION COMPLETION DATE: today’s date
ACTIVATING EXEMPT STUDIES

All signatures are not required prior to activation. These may be activated, however send a note to file, requesting the missing signatures. CRF fields must be updated.

1. Check CRF fields in Admin CORE (under Protocol Setup): Oncology Administration/Entry/Protocols/Protocol Setup
   - Enter Protocol # to Activate
   - Click on CRF tab (3rd tab)
   - Make sure all fields below are updated:
     1. Patient Care Coverage Analysis: EXEMPT
     2. Patient Care Contract/Grant: NOT APPLICABLE
     3. Research Ticket: NOT APPLICABLE
     4. PI Signature Date of Coverage Analysis: DATE
     5. CMS Qualified: NO

2. To activate in Admin CORE:
   - ACTIVATION DATE: today’s date
   - check REGISTRATION IS NOT REQUIRED box

3. To activate in Web CORE:
   - DATABASE
   - ENTER PROTOCOL #, then PROT. SEARCH
   - DATA ENTRY TAB
   - UNDER REGULATORY ACTIONS, ACTIVATION DOCUMENTATION
   - ACTIVATION INITIATION DATE: today’s date
   - COVERAGE ANALYSIS COMPLETE: today’s date
   - CONTRACT/GRANT COMPLETE: today’s date
   - RESEARCH TICKET COMPLETE: today’s date
   - All other fields: check n/a box.
     - If ICD, enter today’s date in ICD EDITOR CHECK COMPLETE
     - If ICD translation is required, enter today’s date in ICD TRANSLATION COMPLETE

UNDER ACTIVATION CHECKLIST:
APPROVALS

Evanna Thompson, Director, OPR&R