CHAPTER #7
Study Participant Recruitment and Privacy Issues

7.1 Recruitment and Retention Planning .................................................. 85
  7.1.1 The Clinical Trials Participation eQuation (CTPQ) .................... 85
  7.1.2 The Recruitment Funnel or “Leaky Pipe” Framework ............. 88
  7.1.3 Connecting the Dots ............................................................... 90
  7.1.4 Recruitment Resource Plan .................................................. 91
  7.1.5 Recruitment Action Plan ....................................................... 92
  7.1.6 Best Practice Considerations ............................................. 93
7.2 Advertisement .................................................................................. 93
7.3 Informed Consent ........................................................................... 94
7.4 Patient Privacy and Data Security .................................................. 94
  7.4.1 HIPAA and research activities ............................................. 94
  7.4.2 De-identified patient information using Cohort Discovery Tool .................................................. 95
  7.4.3 Requesting Access to Protected Health Information (PHI) Data .................................................. 96
  7.4.4 Disclosure Tracking Database .............................................. 98
7.5 Submit Copy of Consent to Health Information Management (HIM) .................................................. 99
7.6 Payment to Subjects and W9 ......................................................... 99
7.7 Drawing blood for research subjects ............................................. 100
7.8 Performing CLIA Waved Diagnostic Tests .................................... 101
7.9 Subject Injury and Complications .................................................. 101
CHAPTER 7: Study Participant Recruitment and Privacy Issues

7.1 Recruitment and Retention Planning

This section will introduce two theoretical frameworks as well as some practical planning tools that will enable more successful recruitment and retention. Successful recruitment and retention is a function of effective planning. Research teams need to know:

- HOW many patients they can realistically enroll within WHAT time period?
- WHERE the patients will come from (i.e., the main sources of patients)?
- HOW the patients will be identified (i.e., what study awareness and outreach tactics will be used)?
- HOW the patients will be consented, screened and retained?
- WHO will create and develop the various materials needed?
- HOW much of all the recruitment and retention efforts will cost and WHO will pay for these?
- WHEN and WHERE will the various tactics be deployed?
- HOW will we know what is and isn’t working and WHAT should be done to get enrollment back on track (or reduce the number of drop-outs) should the plan fail?

7.1.1 The Clinical Trials Participation eQuation (CTPQ)

Even with hundreds of ideas for enhancing patient recruitment and retention, it is difficult to know where to start. One of the frameworks for organizing the ideas is called the Clinical Trials Participation eQuation (CTPQ).

The CTPQ Formula states that a subject’s willingness to sign on to, and stay in a clinical trial is a function of the following:

**Numerator:**

- Subject’s awareness of the study opportunity and the extent to which they feel their participation is appreciated – by the sites and research sponsor
- Extent to which the subject is educated and informed about clinical trials in general, and about the specifics of the given clinical trial. It also includes expectations of benefitting from the trial, and the anticipated/experienced comfort and quality of the clinical research environment.

---

1 This Chapter is authored by Beth Harper, BS, MBA, President of Clinical Performance Partners, Inc. and previous guest lecturer at UC Davis Coordinator training programs, Ms. Harper developed these models through her extensive experience conducting clinical trials as well as troubleshooting studies where recruitment falls behind.
• **Credibility** of the site staff conducting the trial and staff’s interaction with the subject.

• **Strength** of the relationship the site has with the subject and site’s responsiveness to subject inquiries and needs. This also includes resources available to (or impact on financial resources of) the patient/family.

• **Nature** and frequency of communication between the subject and key site staff.

**Denominator:**

• The amount of risk or peril and inconvenience associated with participation in the study as well as the strength and impact of key influencers (e.g., GP, family members) on the subject’s decision to participate.

---

The formula helps to understand the factors that influence a subject’s willingness and ability to participate in a trial and to deploy key “levers” to minimize drop-outs.

In essence, to get a patient to participate and stay in a trial, one must balance out all of these factors. Where possible, researchers should try to minimize the amount of risk and inconvenience, and to address concerns from potential influencers like other family members, primary care physicians, spiritual leaders or others.

Since the “Perils and Inconveniences” (P/I) factors are often a function of the protocol and harder to influence or control, it’s often necessary to do a lot more of the “Awareness/Education and Credibility/Relationships/Communication” (AE and CRC) to overcome the impact of the “P/I”. For particularly challenging studies, the study team has to do more awareness building, more appreciating, more educating, more relationship building in order to ensure a subject will consider, enroll and stay in the study.
It's often tempting to solve the patient recruitment problem by just focusing on one of the elements, such as awareness of study opportunity. In reality, this is only 1/7th of the equation. All of the other elements must also be addressed to ensure recruitment and retention. The emphasis one places on each of the elements will vary by indication, protocol, site and patient population. Go through the elements systematically, and ask the following questions:

1. How will participants be aware of the study?
2. How well educated is our population about their disease and clinical research? Will we need supplemental educational materials?
3. When, how and how often will our population want to be communicated with?
4. What financial or other resource constraints or concerns might impact their willingness to participate?
5. What kinds of things could we do to make the study less inconvenient (or what could we do to minimize the inconveniences)?
7.1.2 The Recruitment Funnel or “Leaky Pipe” Framework

Another way to think about recruitment and retention planning is through visualizing the recruitment funnel. The “leaky pipe” framework comes from supply chain methodology, which describes inputs into and outputs of the process. In case of a clinical trial, the input is a potential pool of available subjects. The output is the number of evaluable subjects who complete the trial and whose data can be used in the study analysis.

The “leaky pipe” process helps researchers to visualize where along the continuum they may lose patients. It also helps to determine the overall conversion ratio from the available pool of patients with a disease or condition to those who are likely to qualify, enroll and stay in the trial. Understanding of the loss ratios and the underlying reasons helps to reduce the loss of patients through various strategies such as modifying inclusion/exclusion criteria, developing patient educational programs, providing transportation assistance etc.

Below is the visualization of the recruitment funnel:

Ideally, researchers should capture the metrics in a systematic way so that they can apply lessons learned from one study to the next. In the absence of historical performance data for a given therapeutic area, indication or phase of trial, applying some of the typical benchmark information can be helpful as a starting point.
On average, a researcher must identify or reach about 10 times as many patients with a given condition in order to randomize one. To randomize 9 patients in a trial, the study will need to reach about 90-100 at the “top of the funnel”. This is because only 1/3 of the patients will meet the pre-screening criteria. About 13% of the starting subjects will accept the opportunity to participate, and only 7% will be randomized.

Researchers are often overly optimistic about their enrollment potential. By evaluating where and how many patients may be lost across the recruitment funnel, researchers can identify the specific methods to either “fill the funnel”, “manage the leaks,” or both, in order to maximize the overall conversion of subjects through the clinical trial process.

The recruitment funnel calculator (excel spreadsheet) [http://www.ucdmc.ucdavis.edu/clinicaltrials/StudyTools/StudyTools.html] is a practical tool that enable to run various scenarios to estimate the conversion ratio for a particular trial.
Example of Recruitment Funnel Calculations:

The Recruitment Funnel Calculations illustrate the parameters and stages involved in the recruitment process. The values shown in the funnel calculations include:

- **Enrollment Period (months):** 12
- **# of Sites:** 1
- **# Patients at a Given Site with Diagnosis or # Patients Available Across All Sites:** 100
- **% Lost During Pre-Screening:** 0.69
- **% Decline to Participate:** 0.58
- **% Lost During Screening:** 0.32
- **% Drop-out Post Randomization:** 0.18

The funnel calculations also show the projected values for patients available, pre-screen qualified, consented (enrolled), randomized, completed, and enrolled per month. The available randomized ratio is 11 to 1.

### 7.1.3 Connecting the Dots

Taken together, the CTPQ and “Leaky Pipe” frameworks can help to plan appropriate recruitment and retention strategies. For example, if you anticipate a need to “fill the funnel” with patients beyond the existing pool, then you will need to do a lot of “A, E and C” (a lot of awareness building, communicating and educating of the public and referring physicians). “Managing the leaks” requires a lot of “CRC”, some “E” and a reduction of “PI” where possible. In other words, strategies and tactics to reduce the number of patients who decline the opportunity requires a lot of credibility of those communicating with the subjects and their family, additional education and an emphasis on relationship building and responsiveness. Ensuring the patient has sufficient resources (e.g., transportation assistance) and reducing the amount of inconvenience through more flexible visit hours are all ways to enhance overall participation.

Each study is unique; while some studies require more efforts to reduce drop-outs, others require more efforts at awareness building and so on. Thinking through the anticipated recruitment challenges will enable strategies and tactics to incorporate into your recruitment and retention plan.
7.1.4 Recruitment Resource Plan

With a realistic idea of how many patients are needed and enrollment and retention hurdles, creative planning process can begin Recruitment Resource Plan (RRP) ([http://www.ucdmc.ucdavis.edu/clinicaltrials/StudyTools/StudyTools.html](http://www.ucdmc.ucdavis.edu/clinicaltrials/StudyTools/StudyTools.html)) outlines the planned approach to recruiting and retaining subjects. This analysis has an effect on a budget for the proposed recruitment and retention strategy. A sample RRP is included below and provides the basic areas to include in the plan. When shared with the research sponsor or submitted as part of a grant application, RRP demonstrates that due diligence is completed. RPR contains the realistic enrollment and associated efforts and activities to fulfill the enrollment goal. The RRP answers some of the fundamental planning questions of where the patients will be identified and how, and what materials and methods will be used and how much they will cost.
7.1.5 Recruitment Action Plan

Similar to the RRP, a Recruitment Action Plan or RAP, is a simple document that outlines the “who, what, when and where” aspects of the plan. When and where will specific tactics or initiatives be deployed and by whom? What is the outcome of the efforts and how is enrollment progressing? This provides visibility and transparency across all members of the team (site personnel, CRO and sponsor personnel if appropriate, management). If the goal is not being achieved, the form allows to evaluate what is and isn’t working to make necessary adjustments.

Reviewing the RRP and RAP as part of a post study analysis can provide valuable insights and the documents can then be applied to future studies to streamline the planning activities for the next trial. The modifiable RRP and RAP templates can be downloaded at http://www.ucdmc.ucdavis.edu/clinicaltrials/StudyTools/StudyTools.html
7.1.6 Best Practice Considerations

Here are some practical tips and considerations for applying the frameworks through various stages of recruitment and retention planning and implementation:

**During the feasibility assessment (protocol development) stage:**

- Use the CTPQ to think through all of the possible factors that might impact successful study participation
- Discuss with the entire team and get consensus on which factors will be an issue for the trial
- Rate and rank the factors that have the greatest likelihood of making a difference (lowest scores)
- Determine WHAT action could be taken and estimate HOW MUCH it would cost to address these issues
- Collectively agree on which initiatives should be incorporated into the budget and recruitment action plan

**Tips for “rescuing studies” behind in enrollment:**

- Use the CTPQ to help evaluate potential root causes from the patient perspective
- There may be other protocol, sponsor, financial issues to consider
- Determine which factors are at play and again, rank and rate the impact on enrollment
- Brainstorm on possible interventions or solutions for each of the factors that are most likely to have an impact (the lowest scoring items)
- Determine as a team which interventions to pursue and put in place an action plan [approvals, budget, materials, etc.]
- Monitor progress and re-visit the CTPQ periodically

**Tips for post-study “lessons learned” analysis:**

- Conduct a “post-hoc” lessons learned session
- Comment on what worked, what didn’t and why…what could be done differently next time
- Look at the patterns and issues across studies
- Use the formula and lessons learned as a starting point for future trials to address the most common factors next time!

7.2 Advertisement

The UC Davis IRB must review and approve all materials for human subject recruitment before recruitment efforts begin. An advertisement to recruit subjects is any form of materials whose main purpose is to inform and invite potential subjects to participate in a research study, including:

- Flyers and handouts
- Bulletin boards/Billboards
- Letters and e-mails
- Newspapers/magazine Ads
- Posters
- Radio, TV and Cable
- Website/Internet postings
- Phone scripts
- Facebook
The advertisement should be limited to the information prospective subjects need to determine their eligibility and interest, such as:

- Name and address of the investigator or research facility;
- The condition under study or purpose of the research;
- In summary form, the criteria that will be used to determine eligibility for the study;
- A brief list of participation benefits, if any;
- The time or other commitment required of all subjects;
- The location of the research and the phone number of the person or office to contact for further information.

For FDA-regulated research, the advertisement should not:

- Make claims, either explicitly or implicitly, that the drug, biologic or device is safe or effective for the purposes under investigation.
- Make claims, either explicitly or implicitly, that the test article is known to be equivalent of superior to any other drug, biologic or device.
- Use terms, such as “new treatment,” “new medication” or “new drug” without explaining that the test article is investigational.
- Include a coupon good for a discount on the purchase price of the product once it has been approved for marketing.
- State or imply a certainty of favorable outcome or other benefits beyond what is outlined in the consent document and the protocol.
- Promise “free treatment,” when the intent is only to say subjects will not be charged for a taking part in the research.
- Include exculpatory language
- Emphasize the payment of the amount to be paid, by such means as larger or bold type.

### 7.3 Informed Consent

Appendix “Informed Consent” delineates requirements and best practices

The Clinical Trials Resource Group provides Informed Consent Bootcamp. Check the schedule for the next availability. The archival slides can be accessed at: [http://intranet.ucdmc.ucdavis.edu/ctsc/area/cttraining/index.shtml](http://intranet.ucdmc.ucdavis.edu/ctsc/area/cttraining/index.shtml)

### 7.4 Patient Privacy and Data Security

#### 7.4.1 HIPAA and research activities

**When does HIPAA apply to research activity?**

When a clinician involved in a patient’s care is considering that patient for research the privacy rules can be confusing. HIPAA (Health Insurance Portability and Accountability Act) applies when patient records are accessed for both treatment and research purposes. In general, under the HIPAA privacy rules, a patient’s medical information may be accessed for a treatment, payment or operational purpose without obtaining prior written consent. However, access to patient records for most other purposes, including research, requires additional steps to be taken to comply with state and federal privacy laws.
When is access considered to be “for a research purpose”?

If a patient’s record is reviewed for a treatment purpose (e.g., to view lab results or consult with a referring provider) the research-related rules do not apply. However, once a patient’s medical information is viewed for a research-related activity (e.g., to screen for eligibility, to review a unique case for possible study, or to collect data) the research-related HIPAA rules apply. For example, if a provider is reviewing a patient’s lab report for regular care, this access would be for treatment purposes and the research-related rules would not apply. However, if during this review, the provider notices that the lab value may make them a potential research subject and wants to review the chart further for eligibility, the research-related rules would must be considered.

What are the research-related privacy rules that should be considered?

In general, patient information cannot be used for research-related purposes without a signed patient authorization. Before any patient information can be used for a research purpose, the patient must sign and date a study-specific HIPAA Authorization for Research form (“Permission to Use Personal Health Information for Research”) which recites the patient’s privacy rights. This is true whether or not the patient is seen by the researcher/physician for medical care.

There are two limited exceptions to needing patient authorization prior to accessing a patient’s record for research purposes:

1. if the IRB has granted a Waiver of Authorization (“Form R” waiver) or,
2. if the researcher has been granted a “Preparatory to Research Authorization.”

If access to a patient’s medical information is pursuant to one of these exceptions, then any access must be documented as an Accounting of Disclosure under HIPAA and tracked in accordance with UCDMC Policy and Procedure 2446, “Tracking Disclosures of Protected Health Information.”

**IMPORTANT**

Any study data obtained without the proper authorizations cited above may not be used for publication (i.e., journals, abstracts, etc.) or any other purpose, and can be subject to notification requirements under state and/or federal laws.

**7.4.2 De-identified patient information using Cohort Discovery Tool**

One way to assess study feasibility or identify a potential subject cohort without obtaining patient consent or seeking a waiver is to access de-identified information. While de-identified data will not give a researcher access to specific, potential subjects, it can help researchers assess the likelihood of patient recruitment within the UCDHS patient population.

The **Cohort Discovery Tool** provides researchers the ability to query several sources of patient data to obtain de-identified information about the patient population. Cohort discovery is a repository of patient information gathered from multiple sources, including electronic medical records, lab results, and demographic data. To register to access Cohort Discovery and for training on its use go to: [http://www.ucdmc.ucdavis.edu/ctsc/area/informatics/cohortdiscovery/](http://www.ucdmc.ucdavis.edu/ctsc/area/informatics/cohortdiscovery/).
While the data initially provided by the Cohort Discovery Tool is de-identified, once a report is run in Cohort Discovery, it is possible for researchers to obtain identified patient data. The IRB approval must be obtained before contacting patients identified by EMR screening. To obtain approval, submit the contact plan with a copy of the script or other correspondence for the contact. Patients expect only individuals who have a treatment relationship with them to look at their medical records. When developing the contact plan, consider the patient’s autonomy, privacy and confidentiality.

7.4.3 Requesting Access to Protected Health Information (PHI) Data

Access to the patient EMR record; Recruitment is permitted; Tracking of disclosure via EMR or online disclosure database is NOT required

Access to EMR records as specified in IRB application; Recruitment is permitted; Tracking of disclosure via EMR or online disclosure database is required

Access to selected EMR records based on inclusion/exclusion criteria; No PHI can be removed from EMR (view only, no printing); Recruitment is not permitted; Tracking of disclosure via EMR or online disclosure database is required

Counts of patients based on the inclusion/exclusion criteria
Option 1. Preparatory to Research Application (45 CFR 164.512(i)(1)(ii))

In some situations, access to de-identified data is not sufficient to determine if a research project is feasible. In such a case, researchers may submit a Preparatory to Research Application to the UCDHS Privacy team seeking approval to review patient records prior to patient consent and/or IRB approval.


For all preparatory requests, the following rules apply:

1. **Attest** that the work is solely to review PHI (protected Health Information) to prepare a research protocol or for similar purposes preparatory to research;
2. **Provide** a statement affirming that **no PHI will be removed** from the covered entity by the researcher in the course of your review. This means that the data retrieved cannot be shared, in an identifiable fashion, with any person or third-party agency; and
3. **Only** access the information necessary to research your research goals in accordance with the Minimum Necessary Rule; and
4. **Agree** that any access to PHI without a signed HIPAA Authorization will be tracked by the individual accessing the information. Specifically, access that is Preparatory to Research must be documented in the Disclosure Tracking Database or within EMR Quick Disclosure Activity.

Clinical Trials Newsletter v.19, 2014 describes the Accounting of Disclosures process and reporting responsibilities (“EMR Quick Disclosure”).

**Special Cases: Decedent Research**

To look at PHI for decedent research where there are no identifiers linked to living persons and no use of vital death records, submit a Decedent Research Application.

The HIPAA Privacy rule protects individually identifiable health information of deceased individuals for 50 years following the date of death.

The application can be found on the Compliance website: [http://www.ucdmc.ucdavis.edu/compliance/](http://www.ucdmc.ucdavis.edu/compliance/). The Privacy Officer may request proof of death.

If the research will include any identifiers linked to living persons or involves accessing death records maintained by the State Registrar, local registrars, or county recorders, the project must also be approved by the IRB in advance. For more information about the Privacy Rule and decedent research provisions go to: 45 CFR 160.103, paragraph (2)(iv) of the definition of “protected health information.”
**Option 2. HIPAA Waiver of Authorization for Recruitment**

A HIPAA Waiver of Authorization can also be obtained from the IRB if access to patient data prior to patient consent is needed for recruitment purposes. To request a Waiver of Authorization, the researcher must describe the need for such access in the protocol template (HRP-503, Section 25 - Recruitment Methods). This section is then reviewed by the IRB. If a full or partial waiver is granted, a researcher may access identifiable patient data only to determine if a patient is a viable research subject. IRB approval is confirmed by issuance of the Form R ("Waiver of Research Participant’s Authorization for Use/Disclosure of PHI for Recruitment"). All access to patient records pursuant to this type of Waiver must be documented as an Accounting of Disclosure in the Disclosure Tracking Database or within EMR Quick Disclosure Activity. See Section 8.2.

### 7.4.4 Disclosure Tracking Database

The Privacy Rule and UCDHS P&P 2446 require an accounting of certain disclosures of protected health information (PHI). This includes chart reviews:

- Prior to a signed waiver of authorization for research form
- Preparatory to research
- For research involving decedents

In accordance with the Privacy Rule, a patient can request that the institution provide him or her with an accounting of these types of disclosures.

Prior to a subject signing the HIPAA Authorization for Research form, any access to patient identifiable data for research purposes must be reported as an Accounting of Disclosure, even if a Preparatory Research Application or HIPAA Waiver of Authorization has been approved.

Recording a disclosure of access to patient records may be documented in one of two ways:

1. In the Disclosure Tracking Database which can be found online at: [http://www.ucdmc.ucdavis.edu/compliance/guidance/research/researchprivacy.html](http://www.ucdmc.ucdavis.edu/compliance/guidance/research/researchprivacy.html). When completing this form, the type of access should be checked as “Disclosures for Research (no authorization).”

2. In the Electronic Medical Record of the patient accessed, using Quick Disclosure Activity. With the Quick Disclosure activity, EMR users can quickly and conveniently record what information they release, all from their clinical workspace.

To access the Quick Disclosure in EPIC:

1. Go to Hospital Chart or Chart;
2. Click “More Activities” and choose Quick Disclosure;
3. Quick Disclosure opens. Fill out the appropriate fields:
   - Purpose Field – type Research and choose the appropriate purpose
   - Info Requested – click on magnifying glass to see all categories
   - Authorization Received – click “Third Party” and type “UCD” in requester field then press enter. (Always indicate disclosure made to the UC Davis Health System)
   - Authorization Received? – Choose “Yes” or “No”

See [CT Newsletter v19, March 2014](http://www.ucdmc.ucdavis.edu/compliance/guidance/research/researchprivacy.html) for description of the Quick Disclosure.
CHAPTER #7

7.5 Submit Copy of Consent to Health Information Management (HIM)

Consent Forms for research are required to be in the Legal Medical Record for drug and device studies. Policy & Procedure 2306 [Legal Medical Record Content/Core Elements] requires that the Informed Consent Form (ICF) must be part of the Legal Medical Record. Under Section VI.E.2.f, [Consents for Care, Treatment and Research/Human Subjects Research involving investigational use of a drug or device], the policy requires that a “signed copy of the consent form is filed in the medical record.”

All consent documents must have the patient’s label or name and medical record number. This will allow HIM to locate the correct patient record and upload the consent form. Place consent documents in the HIM mail baskets located in all patient care areas. Couriers routinely pick these up, and all documents are promptly scanned by the HIM into the medical record. It is important to send the signed ICF’s to HIM as soon as possible since they are held to time standards for scanning documents.

In some cases, it may make sense to establish a local scanner to expedite the upload process. To do so, use an existing scanner, as long as it is properly configured.

1. Create an on-line access request for OnBase Clinical - Scan/Index.
2. Once access is approved, HIM will set up an appointment to install scan software, set up network drive, map your scanner, and train on how to use the scan to HIM.

The scanned documents can be found under the “Media” tab in the EMR. The ICF needs to be scanned and uploaded even if the patient does not pass screening criteria.

Clinical Trials Newsletter v.12, November 2012 provides further details on the process for documenting ICF in the EMR:

Clinical Trials Newsletter v.18, October 2013 describes how to upload Consents into the HIM queue using a local scanner

http://intranet.ucdmc.ucdavis.edu/ctsc/area/ctnewsletters/

7.6 Payment to Subjects and W9

The Institutional Review Board (IRB) determines that the risks to subjects are reasonable in relation to anticipated benefits [21 CFR 56.111(a)(2)] and that the consent document contains an adequate description of the study procedures [21 CFR 50.25(a)(1)] as well as the risks [21 CFR 50.25(a)(2)] and benefits [21 CFR 50.25(a)(3)]. It is not uncommon for subjects to be paid for their participation in research, especially in the early phases of investigational drug, biologic or device development. Payment to research subjects for participation in studies is not considered a benefit, it is a recruitment incentive. Financial incentives are often used when health benefits to subjects are remote or non-existent. The amount and schedule of all payments should be presented to the IRB at the time of initial review. The IRB reviews both the amount of payment and the proposed method and timing of disbursement to assure that neither are coercive or present undue influence [21 CFR 50.20].

Any credit for payment should accrue as the study progresses and not be contingent upon the subject completing the entire study. Unless it creates undue inconvenience or a coercive practice, payment to
subjects who withdraw from the study may be made at the time they would have completed the study (or completed a phase of the study) had they not withdrawn. For example, in a study lasting only a few days, an IRB may find it permissible to allow a single payment date at the end of the study, even to subjects who had withdrawn before that date.

While the entire payment should not be contingent upon completion of the entire study, payment of a small proportion as an incentive for completion of the study is acceptable to FDA, providing that such incentive is not coercive. The IRB determines the amount paid as a bonus for completion is reasonable and not so large as to unduly induce subjects to stay in the study when they would otherwise have withdrawn. All information concerning payment, including the amount and schedule of payment(s), should be set forth in the informed consent document.

For additional information see FDA’s Guidance for Institutional Review Boards and Clinical Investigators; Payment to Research Subjects – Information Sheet at [http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm](http://www.fda.gov/RegulatoryInformation/Guidances/ucm126429.htm)

As of fall 2013, signed W-9 forms are required for all vendors who are individuals or are companies providing a service. This includes study participants receiving payments by check (*gift cards, if in small number, are not a subject to W9 form requirement*). The information captured on the W-9 form is used to ensure UC Davis has the proper identification (address and Tax ID number) for the individual or company being paid. The form also requires a signature of the payment recipient that certifies the information provided is correct under penalty of perjury. This is needed to protect the university from further fines and is something a departmental form cannot provide. Human subjects are entered as vendors in the Kuali Financial System Vendor Tables (not to be confused with vendors who sell to the university and are subject to registration in RepTrax.). Payments in excess of $600 may require additional federal and State taxes for the individual.

For questions related to this change, contact Accounting and Financial Services on UC Davis campus at vendordesk@ucdavis.edu or 530-752-0370 or see website: [http://afs.ucdavis.edu/our_services/contracting-services/vendor-on-boarding/w9-instructions.html](http://afs.ucdavis.edu/our_services/contracting-services/vendor-on-boarding/w9-instructions.html)

7.7 Drawing blood for research subjects

In California, Phlebotomy certifications are governed by CA Professional and Business Code 1246. At UCDHS, the Hospital Patient Care Standard XIII-29 “Venipuncture” outlines who can draw blood in the licensed facilities. Those individuals include Physicians, Nurses, Medical Assistants under Physician supervision and Certified Phlebotomy technicians.

It is a best and prudent practice for research personnel operating in unlicensed facilities to be certified as Phlebotomy Technicians to draw blood. The Certification regulations are governed by California Code of Regulations §1034 and can be found at [http://www.cdph.ca.gov/programs/ifs/Pages/Phlebotomist.aspx](http://www.cdph.ca.gov/programs/ifs/Pages/Phlebotomist.aspx).

Individuals with over 1040 hours (6 months or more) of phlebotomy experience would only need to take a minimal additional training. Only twenty (20) hours of on-line advanced classes are required through the Contra Costa Medical Career College on line school ([https://online.ccmcc.org/](https://online.ccmcc.org/)), followed by 50 successful venipunctures and 10 successful skin punctures. No externship is required. To be eligible for advanced courses, the applicant needs to provide the California experience document signed by an MD or Laboratory Director (suggested form [http://www.cdph.ca.gov/programs/ifs/Pages/Phlebotomist.aspx](http://www.cdph.ca.gov/programs/ifs/Pages/Phlebotomist.aspx)).
Experience must involve on the job experience on real patients.

Individuals with some phlebotomy experience may still be eligible for on-line courses; individual cases are best discussed with CDPH- Laboratory Field Services.

Individuals with no prior phlebotomy experience are not eligible for on-line courses and would need to take a full course at the MTI College in person (basic + advanced) didactic classes and 40 hours of externship.

### 7.8 Performing CLIA Waved Diagnostic Tests

Clinical Laboratory Improvement Amendments (CLIA) of 1988 are United States federal regulatory standards that apply to all clinical laboratory testing performed on humans in the United States (42 CFR 493). The UCOP legal analysis of the California Business and Professional Code § 1200 governing CLIA (Clinical Laboratory Improvement Act) regulations is presented below.

According to the UCOP interpretation, unlicensed personnel may not collect biospecimens by doing skin punctures (e.g., they cannot withdraw blood or perform glucose tests that involve finger pricks).

Unlicensed personnel may collect other kinds of biospecimens, but they cannot perform all components of waived point-of-care testing. Specifically, unlicensed personnel may not record test results (though they can transcribe results that have been previously recorded by an instrument), perform any test or part thereof that requires a quantitative measurement, or calibrate instruments.

- **Glucose test**: Study subjects can perform finger pricks on themselves, and the unlicensed personnel can transcribe the results generated by the automated instrument (B&P Code § 1241(b)).
- **Pregnancy test**: The most reasonable interpretation of the B&P Code is that a CRC can provide the patient with the pregnancy test but cannot read or record the results (B&P Code § 1269(d)-(e)).
- **Urinalysis**: For a urine dipstick test, a CRC may add the dipstick to the urine specimen but may not read or record the results (B&P Code § 1269(e)).

### 7.9 Subject Injury and Complications

While clinical sites, such as UC Davis, typically provide medical treatment to subjects sustaining injury/complication on a study, a party that will cover the costs may not always be a clear. Industry sponsor, insurance or even self-pay options are considered.

For privately sponsored studies that are conducted pursuant to a private sponsor’s protocol, the sponsor of the study is required to pay for the reasonable cost of treating injuries/complications resulting from participation in the study, including injuries/complications resulting from the study material or research procedures performed pursuant to the study protocol, to the extent that injuries/complications were not a result of negligence, willful misconduct or failure to reasonably act on the part of the study personnel (UC Operating Requirement 95-05, 13-01). Other costs that are incurred during conduct of the study but not directly resulting from the subject’s participation (i.e., typical for this type of disease or procedure) may be billed to private and government insurers, if consistent with their policies. However, in the case of injuries resulting from the
natural progression of a disease or illness, the sponsor would be responsible for any injuries if, and to the extent, the progression resulted from participation in the study. In some cases, determination of whether the complication was directly or indirectly related may not be clear.

**Example:**

If an investigational medication is administered via an intravenous infusion, and the needle entry site became infected, it does not necessarily mean that this injury is directly related to the investigational drug administration. Other factors need to be considered. For instance, if the standard of care or alternative treatment is an oral medication, then the i.v. infection may be directly attributed to the investigational study drug. However, if the standard of care treatment is also intravenous, then the infection maybe construed as being a consequence of this typical intravenous procedure, and therefore, not directly related to the investigational drug administration.

Contact UC Davis Risk Management risk.management@ucdm.ucdavis.edu or (916) 734-3883 for help with determination.

When the trial is not conducted pursuant to a private industry sponsor protocol, the costs of treating study subjects for injuries/complications directly resulting from a study material or research procedures may be responsibility of the University or Medicare/private insurance plans, depending on whether the injury resulted from a research procedure designed to benefit the subject directly. Generally, Medicare and other health plans require proof of therapeutic intent and medical necessity for coverage of clinical trial costs and the University Subject Injury Policy will not pay or reimburse the participant for any injuries resulting from medical research procedures designed to benefit him or her directly.

For more information, contact Risk Management as directed above.