

**IRB Guidance: Recruitment, Referral and Screening of Research
 Participants, Advertising, & Incentives**

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INTRODUCTION

This guidance provides information related to research recruitment, referral, screening, advertising, and incentives.

This guidance represents the IRB’s current thinking on this topic; however, the use of the word “must” in this document means the concept is a Downstate policy or regulatory requirement.

The use of the word “*should*” in this document means the concept can be treated as guidance or something is recommended or suggested, but not required. An investigator may use an alternative approach if the approach satisfies regulatory requirements.

The following individuals are available as Consultants to the IRB or Investigators for questions or guidance:

Topic	Resource	Contact Information
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General Questions	Downstate IRB	https://research.downstate.edu/irb/members.html irb@downstate.edu
Privacy and HIPAA	Downstate Privacy Officer or Office of Compliance and Audit Services	shoshana.milstein@downstate.edu alexandra.bliss@downstate.edu compliance@downstate.edu
Social Media Recruitment Ads	Office of Communications & Marketing	dawn.walker@downstate.edu james.gerontzos@downstate.edu john.zubrovich@downstate.edu
Images/Photography	Office of Communications & Marketing	marcos.lainez@downstate.edu
New Media Services	Office of Communications & Marketing	https://www.downstate.edu/news-events/communications-marketing/new-media-services/index.html john.zubrovich@downstate.edu
Graphic Design	Office of Communications & Marketing	Sean.Thill@downstate.edu Frank.Fasano@downstate.edu
Marketing	Office of Communications & Marketing	James.Gerontzos@downstate.edu
Legal	General Counsel	william.versfelt@downstate.edu lynne.reid-mcqueen@downstate.edu

RECRUITMENT, REFERRAL AND SCREENING OF RESEARCH PARTICIPANTS

Unless an activity falls under an exception (some are described herein), a Downstate researcher may only review Protected Health Information (PHI) and individually identifiable private information for the purposes of gathering information for recruitment purposes, if a HIPAA Waiver is approved by the Downstate IRB & Privacy Board (IRB) or the Downstate Privacy Officer. For FDA regulated clinical investigations and non-exempt DOJ funded research, a Waiver of Informed Consent must also be approved by the IRB.

For all other non-FDA and non-exempt research, the IRB must either approve a waiver of informed consent or the IRB may approve a process in which the investigator obtains information through oral or written communication with the prospective research participant or the surrogate (e.g., Legally Authorized Representative) or a process in which the investigator obtains identifiable private information or identifiable biospecimens by accessing records or stored identifiable biospecimens.

CLINICAL REFERRALS OF RESEARCH PARTICIPANTS

Treating physicians and other members of a patient's treatment team are permitted to review their own patients' health information to determine whether they might be eligible to enroll in an IRB-approved clinical trial or research project.

Treating physicians are permitted to contact their patients about and/or discuss available research options with their patients. Once the treating physician has discussed the options with their patient, the treating physician may obtain their patient's informed consent if they are also the researcher or refer the informed consent process to another investigator on the study team.

Neither a partial HIPAA waiver nor a waiver of informed consent is required for recruitment activities in this situation; however, the clinician or his/her treatment personnel should note the communications regarding prospective participation in a research study in the patient's medical record, as described below. A HIPAA Authorization or a HIPAA waiver may still be required for any remaining use of PHI in the research.

A clinician (or clinician's treatment personnel) who is not the researcher may do any of the following without requesting a HIPAA Waiver or Waiver of Informed Consent:

- Approach their patient about participation in another investigator's researcher's IRB-approved study. The communication about the potential research activity should be noted in the patient's medical record. If the patient agrees to a referral to the researcher, the suggested language for the medical record is: "I discussed the referral of the patient to [name of Principal Investigator] for [describe research study]. The patient agreed to the referral, including sharing his/her contact information, and information their condition." However, it is preferred that the clinician use one of the **following** [Research Subject Recruitment Authorization Forms](#), to obtain contact information for patient recruitment through their clinicians. Download in PDF format and click "Highlight Existing Fields" in upper right corner to edit. To use these forms refer to [Policy HIPAA-28 Use and Disclosure for Research Purposes](#). Submit the completed forms (without patient information) for IRB approval. The following forms are also available at Step 8 on the [IRB Submission website](#):
 - Subject Recruitment Authorization - Internal Authorization for Recruitment Contact
 - Subject Recruitment Authorization - Internal Verbal Authorization for Recruitment Contact
 - Subject Recruitment Authorization - External Authorization for Recruitment Contact
- Give their patient an investigator's name and contact information to allow the patient to contact the Investigator directly.
- Discuss possible patient eligibility with the research personnel in a de-identified manner (i.e., with all identifiers removed). If the research personnel believe the de-identified patient would be eligible for the trial, the treatment personnel could then obtain the patient's permission to give the research personnel the patient's name or give the patient the researcher's contact information.
- Send an IRB approved letter to their patient about how to join an IRB approved study. **This type of letter may NOT be co-signed by the researcher and the researcher may not have a copy of the letter addressed to the specific patient, unless the IRB approves a HIPAA Waiver and Waiver of Informed Consent to review the records for recruitment purposes.**

Alternative approaches will be considered by the IRB on a case-by-case basis. The IRB will consider best practices and level of risk when reviewing the alternative approaches.

PREPARATORY TO RESEARCH ACTIVITIES

Sometimes it is useful to review patient data to understand whether there would be an adequate number of patients for data analysis or to determine if there enough patients to potentially enroll them into a research study.

Example: An investigator needs to determine if she will have enough patients with sickle cell trait among the patient population, they can review medical charts to determine how many sickle cell trait patients are documented in the medical records; however, they cannot contact the patients or record any identifiers.

If an activity is limited to a "preparatory to research activity" (e.g., review of protected health information in preparation for research to determine if there are enough patients to recruit or records to review), IRB approval is not required; HOWEVER, if someone other than the patient's clinicians are accessing the patient records, they must complete a "[Research Certification for Reviews Preparatory to Research form.](#)"

Under the HIPAA regulations this form is used to document the activity. It can be saved in the research records and provided to the IRB when an IRB application is submitted. The form will be requested by HIM if the investigator wanted to review manual charts.

Under the Common Rule this activity is "exempt" because identifiers are not recorded. Because Downstate, by policy, require IRB review of exempt research, we have a statement in our IRB-01 policy that we automatically consider "preparatory to research activity" to be exempt and it does not need advance approval by the IRB.

CAUTION: When carrying out a "preparatory to research activity" **HIPAA identifiers CANNOT be recorded!!!** For more information about this, refer to the de-identification standard within the [Policy HIPAA-6: De-Identification of Information.](#)

The use of the Preparatory to Research process does NOT permit the continued use or disclosure of the protected health information once the Principal Investigator has determined to go forward with the study. IRB approval is required before the study can begin.

RECRUITMENT BY FAMILY MEMBERS OR OTHER RESEARCH PARTICIPANTS

When recruitment strategies involve the recruitment of participants by family members or currently enrolled research participants (e.g., snowball sampling recruitment) the specific details of such strategies must be approved by the IRB.

HIPAA WAIVERS AND WAIVER OF INFORMED CONSENT FOR RECRUITMENT PURPOSES

In general, when patient records or data are reviewed for recruitment purposes, a partial HIPAA waiver and a waiver of informed consent must be prospectively approved by the IRB, unless recruitment occurs as follows:

- A researcher may review protected health information (PHI) or individually identifiable private information for the purposes of gathering information for recruitment purposes when the researcher is also member of the treatment staff of the potential research participant; or

- A member of the treatment staff may contact their patients about and/or discuss with their patients available clinical research options.

A partial HIPAA waiver (which can also be used to document a waiver of informed consent) can be used to review medical records of patients for recruitment purposes, when an investigator is not the clinician of a patient. Whenever possible, the patient's attending should be having the initial discussion with the patient and determining interest before providing the info to the researcher. In certain cases, the IRB may approve direct communication with certain requirements. For example, the IRB may want to consider the following recruitment options: 1) whether a letter must be sent to the patient from their Clinician or Department Chair 2) whether "cold calls" are prohibited or allowed, 3) whether an investigator can contact the patient directly, 4) whether the patient should be asked to contact the researcher if they are interested in the study. The recruitment methods must be fully described in the IRB application for the IRB to consider on a case by case basis.

When a (Partial) HIPAA Waiver is submitted to the IRB, the IRB may use the information on the HIPAA Waiver Form to grant a Waiver of Informed Consent.

The Investigator must ensure the patient has not 'opted out' of the facility directory before sending any communications to the patient.

The directory/opt out process is described below. The 'Release' field in Eagle will be populated with 'N' for patients who have opted out. **It may be best for Investigators to contact UHB /Admitting/Patient Information (718) 270-1000 / (718) 270-4031 to ask if a patient as opted out (and avoid access to the health information in Eagle).**

II. DOWNSTATE DIRECTORY INFORMATION

The patient's location (phone # and room #), as well as the patient's general condition (poor, good, critical) may be disclosed to any individual who requests about a patient by name. Religious affiliation may be disclosed to clergy. However, the patient may "opt out" of being included in the directory, which would prohibit staff from disclosing any information to any requestor.

A patient who opts out of being included in the directory must complete the "Facility Directory" form. In addition, the following procedure should be followed to enter the patient's opt out request in Eagle:

1. For patient admissions, access the "Admission Maintenance" screen.
2. In the "Release" field, enter "N".

```
04/01/03 04:16PM  DAB TESTING ENVIRONMENT (TEST)  ADMISSION MAINTENANCE
ADM# :                NAME:                SEX/DOB:
SSH :                ADDR:                LOCN:
===== PRM-SEC F/C:
ADMIT DATE: 07/02/99 FRI JUL 2,1999  DISCHARGE DATE: 07/07/99 WED JUL 7,1999
TIME: 08:47AM  SERIAL#:                TIME: 08:20PM  L-O-S: 5
TYPE: ELE ELECTIVE ADMISSION          TYPE: HOM DISCHARGED TO HOME
SOURCE: PVT PHYSICIAN REFERRAL        LOCATION:
ADMIT SRVC:        ACCOM:                .          PRO:
ADMIT PHYS:        NAME:
DIAGNOSIS:        TEXT:                PCR#:
REFER PHYS:        NAME:
ATTND PHYS:        NAME:                EFFECT DT: 07/02/99
PRIOR HOSP:        ADM:                DSC:                SMOKER:
CURR SRVC:        ACCOM: SP  PEDIAT. MEDICINE-SP-RM & BRD.          PRO:
MOTH/NWBRN:        N-ADM#:                PVT/SVC: P
GUAR LINK:                RELATION: MTR          DNR ORDER: N
ACCID LINK:        ACD/NF/WC:
INF.DIS:          RELEASE: N  MSPDATE:        MCD EXMT          COND:
NOS.INF:          VA AUTH:        MSPREQ :        GOV/RSCH          USDEF10:
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For more information, please see:

- Eagle System: HIPAA Fields:
<https://www.downstate.edu/hipaa/documents/EagleSystemHIPAAGuide.pdf>
- Policy HIPAA-8: Facility Directory:
<https://www.downstate.edu/hipaa/documents/HIPAA.8.FACILITYDIRECTORY.Dec.2016.pdf>

If recruitment takes place at another hospital, follow the process for checking the patient directory for the hospital at the other site.

RECRUITMENT LETTERS OR E-MAILS

All recruitment letters and recruitment e-mails must be reviewed by the IRB.

The Investigator must ensure the patient has not 'opted out' of the facility directory before sending any communications to the patient. See above for process.

RECRUITMENT PHONE CALLS

All recruitment scripts for phone calls must be provided to the IRB. The IRB will stamp the script after it is approved.

The IRB discourages the use of "cold-calls" to potential Research Participants, when the participants do not have a relationship with the research staff (e.g., not their healthcare provider).

The preferred method of contact is to send a recruitment letter/e-mail to the potential research participant, from someone who has a relationship with the potential research Participant or from the Department Chair or Clinical Director letting them know they can contact the research team. **Protected Healthcare Information cannot be included in a non-encrypted e-mail and is discouraged in letters.**

The IRB discourages recruitment methods that include having the research team contact a potential participant, by telephone when they do not respond to a recruitment letter/e-mail; however, the IRB will consider this approach on a case-by-case basis, and approval may depend on the level of risk, considerations for privacy, and content of communications.

The Investigator must ensure the patient has not 'opted out' of the facility directory before calling any patient. See above for process.

SCREENING POTENTIAL RESEARCH PARTICIPANTS TO DETERMINE ELIGIBILITY

Potential research participants may be screened to determine if they are eligible for recruitment and enrollment under the following circumstances:

- A healthcare provider can review the healthcare records of the patients they are treating.
- Screening can take place after informed consent and HIPAA Authorization (if applicable) is obtained, according to an IRB approved process.
- Screening can take place under an IRB approved waiver of informed consent and a HIPAA waiver, if applicable.

Screening logs of de-identified information may be maintained without IRB approval; however, if identifiers are maintained, this must be described in the IRB application materials, including informed consent forms or applicable waivers, and prospectively approved by the IRB.

INFORMED CONSENT

Please refer to [Policy IRB-01](#) and the IRB Guidance document titled: [Obtaining Legally Effective Informed Consent and HIPAA Research Authorization](#).

ADVERTISING

Advertising is considered part of the informed consent process by OHRP and the FDA; therefore, all advertising materials (e.g. newspaper ads, radio ads, TV ads, posters, flyers, internet ads, e-mail announcements, recruitment letters, etc.) must be approved by the IRB prior to posting and/or distribution for studies that are conducted under the purview of the Downstate IRB.

The IRB will review:

- The information contained in the advertisement.
- The mode of its communication.
- The final copy of printed advertisements.
- The script for an audio or video advertisement before it is produced and the final product:
 - When advertisements are recorded for a broadcast, the IRB should review and approve the script prior to recording to preclude re-recording due to any inappropriate wording.
 - The IRB must conduct a review of the final product before it is broadcasted.

Advertisements developed to recruit research participants be limited to the information needed for prospective research participants to determine their interest and potential eligibility. When appropriately worded, the following items may be included in research recruitment ads. The items which are required to be in an ad by the Downstate IRB have a "*" next to them. Many of these items are permissible and optional for advertisements. Many of these items **MUST** be included in the informed consent document or **SHOULD** be included in an information sheet (when consent is waived or a study is exempt) and thus **DO NOT** need to be included in an advertisement.

- *The title of the study.
- *A clear statement that this is "research".
- A clear statement that this is not treatment.
- The name and address of the clinical investigator and/or research facility.
- The condition being studied and/or the purpose of the research.
- In summary form, the criteria that will be used to determine eligibility for the study.
- The time or other commitment required of the research participants.
- The location of the research and the person or office to contact for further information.
- A brief list of potential benefits (e.g. no cost of health exam).
- A statement may indicate that research participants will be paid. The ad should not emphasize the payment or the amount to be paid, by such means as larger or bold type.
- Include link to a survey.
- Include a statement on who to contact for additional information, which may include the study team and/or Downstate IRB.
- Include a statement that the research was approved by the SUNY Downstate IRB.
- The name of the Sponsor. Add a statement such as: "This research is approved by the SUNY Downstate IRB".

The IRB reviews the material to assure accuracy and that it is not coercive, is not unduly optimistic, and does not create undue influence to participate. For example, the following are example of items that **cannot** be approved:

- Statements implying a certainty of favorable outcome or other benefits beyond what was outlined in the consent document and the protocol.
- Claims, either explicitly or implicitly, that the drug, biologic or device was safe or effective for the purposes under investigation.
- Claims, either explicitly or implicitly, that the test article was known to be equivalent or superior to any other drug, biologic or device.
- Using terms like “new treatment,” “new medication,” or “new drug” without explaining that the test article was investigational.
- Promising “free medical treatment” when the intent was only to say participants will not be charged for taking part in the investigation.
- Emphasis on payment or the amount to be paid (e.g., such as bold type or in a font size that is larger than the study title in the ad or an excessive amount that creates undue influence.
- The inclusion of exculpatory language.
- Compensation for participation in a trial offered by a sponsor to involve a coupon good for a discount on the purchase price of the product once it has been approved for marketing.

Here are a few “dos” and “don’ts” to keep the recruitment ad on track:

Do

- Must include accurate grammar, spelling, and punctuation
- Ensure the study team has permission to use images
- Use simple lay language without acronyms or abbreviations that are not commonly known.
- Provide basic exclusion/inclusion criteria (e.g., gender, disease, condition, state, location, etc.) to target the appropriate population.
- Use the word “investigational” rather than “experimental.”
- Specify appropriate compensation (use the phrase “up to” if compensation is pro-rated).

Don’t


- Overly emphasize monetary compensation with bold, italicized, underlined or enlarged fonts.
- Make claims, either explicitly or implicitly, that the drug, biologic, or device is safe or effective for the purposes under investigation.
- Emphasize no-cost treatment if the study includes a placebo.
- Use graphics that convey large sums of money, or benefits beyond reasonable expectations
- Imply a certainty of favorable outcomes or benefits beyond what is outlined in the informed consent
- Promise free treatment, when the intent is only to say that participants will not be charged for taking part in the investigation

When feasible, the IRB approved advertisement must bear the IRB approval stamp. When it is not feasible to stamp the materials, the advertisement must be listed in the IRB approval letter.. Once approved by the IRB, an advertisement or script cannot be altered or manipulated in any way without prior IRB approval.

For more information, see [FDA Recruiting Study Subjects- Information Sheet](#).

ADVERTISEMENT EXAMPLE

Would You Like to be a Part of a Covid-19 Research Study?



DOWNSTATE
HEALTH SCIENCES UNIVERSITY


The Study

We are a group of researchers at SUNY Downstate, Brooklyn, NY. We are studying the effects of the pandemic on people's reproductive and sexual function; for example, changes in menstrual periods, hair growth, and sex drive. This research will help us and the medical community at large better understand the full-body effects of COVID-19.

Eligibility **POSITIVE COVID 19 TEST &**

<p>FEMALES:</p> <ul style="list-style-type: none"> • 18-37 years old • not currently on hormonal birth control, antidepressant, or antipsychotic medication • not pregnant, lactating, or <12 weeks postpartum • no history of radiation, chemotherapy, hysterectomy, b/1 oophorectomy, menopause, eating disorders, hormone therapy, genetic/endocrine conditions (ie: hypogonadism, Turner Syndrome), liver /renal disease 	<p>MALES</p> <ul style="list-style-type: none"> • 25-65 years old • no history / current use of steroids, SSRIs, antidepressants, or hormone therapy • no history or current HIV infection, chemotherapy/ radiation treatment, genital surgery, liver /renal disease, and preexisting genetic/ endocrine conditions (ie: hypogonadism, Klinefelter)
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PLEASE CLICK HERE TO PARTICIPATE



Alternatively, scan the QR code or visit <https://redcap.link/os6x1806>

If you have any questions or feedback, please contact the principle investigator:
Dr. Ozgul Muneyyirci | (718)-270-2101
ozgul.muneyyirci-delale@downstate.edu

LOGOS

It is recommended (not required) that one of the Department logos (e.g., STAR or Children's Hospital logos) or one of the Downstate logos is included in any advertisement. When possible the logo should be centered at the top of the advertisement. The Downstate logos may be downloaded from: [New Media Services | SUNY Downstate Health Sciences University](https://www.downstate.edu/news-events/communications-marketing/new-media-services/index.html) or URL: <https://www.downstate.edu/news-events/communications-marketing/new-media-services/index.html>

The primary logo and horizontal logos are provided below:



GRAPHIC DESIGN

New Media Services provides a fee-based service to help with the design of the advertisement. For more information, see: [Art & Graphic Design | SUNY Downstate Health Sciences University](#).

TYPOGRAPHY

The primary typeface is Lora. This typeface works best in its regular weight, which is made to be distinctive and clear. Lora is used for all headlines and large text. The secondary typeface is Montserrat, which was chosen for legibility in large blocks of text. Montserrat is used for small subheads or notes in its bold weight or for body copy in its regular weight.

Never use Lora for body copy or Montserrat for headlines. The relationship between these two type families must be maintained at all times.

For more information see: [Typography | SUNY Downstate](#)

In the case that these fonts can't be installed or they're unavailable to you, the guidance is to use "Georgia" for headings and larger text and "Verdana" for body copy. These were the system alternatives that were chosen to closely match the new fonts.

COLOR

The color palette is an integral part of Downstate's brand identity. The identity relies primarily on a rich "Downstate" navy, and a dark royal blue. Secondary colors include indigo, sea green and shade tints of gray.

The rich "Downstate" navy blue plays a prominent role in headlines and in creating dark backgrounds for lighter text to stand out on. The sea green and purple is used in areas that draw attention, such as in text highlights, calls to action, banners and callouts. Secondary colors should only be used in limited doses throughout layouts as needed to add interest or variation.

For the full color pallet see: [Color | Graphic Design | New Media Services | SUNY Downstate](#)

SHARING LARGE ADVERTISEMENT FILES WITH THE IRB

If a file is too large to load into IRBNet, it may be shared in OneDrive and shared with the IRB staff. The IRB may need to share this file or ask the investigators to share with others, including IRB Members, General Counsel, Office of Compliance and Audit Services, or the Office of Communications & Marketing.

IRB REVIEW OF CLINICAL TRIAL AND OTHER WEBSITES

Whether or not IRB approval is required for a website would depend on the information that will be posted on the website. Basic descriptive information included below would not need IRB approval:

- Study title
- Purpose of the study
- Protocol summary
- Basic eligibility criteria
- Study site location(s), and
- How to contact the study site for further information.

When the information posted on the website goes beyond the above information, or includes descriptions of risks and potential benefits, or solicitation of identifiable information, IRB approval is required.

RECRUITMENT INCENTIVES

Payment to research participants may be an incentive for participation or a way to reimburse a research participant for travel and other experiences incurred due to participation. However, payment for participation is not considered a research benefit.

Regardless of the form of remuneration, the proposed payment, method, and timing must not place participants at risk of coercion or undue influence or cause inequitable selection.

Payments should reflect the degree of risk, inconvenience, or discomfort associated with participation. The amount of compensation must be proportional to the risks and inconveniences posed by participation in the study.

The proposed payment should be reasonable and commensurate with the expected contributions of the research participant.

Include the terms of the participation and the amount of payment in the informed consent form. For guidance on informed consent, please see the [IRB Guidance: Obtaining Legally Effective Informed Consent and HIPAA Authorization](#).

Payments should be fair and appropriate, and not constitute (or appear to constitute) undue pressure to volunteer for the research study.

When the research is sponsored by the Department of Defense (DoD), and involves U.S. military personnel, the PI must ensure all DoD requirements are met, including making sure the incentives do not exceed the limitations on dual compensation based on DoD requirements.

The IRB must review both the amount of payment and the proposed method of disbursement to assure that neither entails problems of coercion or undue influence.

Credit for payment should accrue and not be contingent upon the participant completing the entire study. Any credit for payment should accrue as the study progresses. The IRB does not allow the entire payment to be contingent upon completion of the entire study. Payment of a small portion as an incentive may be allowed upon completion of a study when such incentive is not coercive.

The consent form must describe the terms of payment and the conditions under which research Participants would receive partial payment or no payment (e.g., if they withdraw from the study before their participation is completed).

REASONABLE MONETARY COMPENSATION

Payments to research participants through the course of the study must be disclosed within the informed consent document, including the methods, amounts, and schedule of any compensation provided. The amount of compensation should be reasonable and adequate based on the study procedures, the participants' efforts, and the nature of the study population under recruitment. The payment may be proportional to the risks or type of the study. For example, payments for participation in a randomized clinical trial to evaluate the safety and efficacy of an investigational drug would reasonably be expected to be much higher than payments that are provided to someone who is enrolled into a survey for social behavioral research. Regardless of the type of research, **the amount must not be so out of proportion to the participants' efforts that the amount unduly encourages potential participants to do something that is unreasonably against their interests or the interest of the community, or unduly encourages them to do something that they would not otherwise voluntarily choose to do. The payment or reward cannot be so excessive, unwarranted, inappropriate, or improper, that were it not for the offer, the participant would not enter**

the study (or withdraw early), given their better judgement about the risks and procedures involved in the research.

Conversely, low payments may be viewed as exploitation or taking unfair advantage of research participants when they are not offered adequate compensation or other benefits as compared to the value of their contribution, including the burden of participation, their time, inconvenience, and opportunity costs.

Insurance cost-sharing obligations of research subjects, including copayment, coinsurance, and deductible amounts, must not be reimbursed.

All expenses must be included in the research budget. Monetary compensation may be negotiated with the sponsor when developing the budget.

SUNY RF PAYMENT CONSENT

When providing payments (including travel reimbursement) or either 1) \$600 or more per calendar year, or 2) more than \$100 per study visit, please include the SUNY RF Payment Consent with the IRB application materials.

PAYMENTS TO CHILDREN OR PARENTS RELATED TO RESEARCH PARTICIPATION

Appropriate compensation of children may involve additional considerations and may be viewed differently for children and adolescents. While it may be acceptable to compensate some adolescents monetarily, similar to adults, it may be more appropriate to compensate younger children in another manner. Monetary compensation for participation of younger children may be provided to the parents for the time and inconvenience to them associated with their child's participation. Although parents will have expenses for travel, babysitting for siblings, time off work to bring children in for appointments, it should be recognized that the children are research participants. Children may undergo stress, discomfort or inconvenience as a result of participation in research studies, and there should be some effort made to compensate the children directly and personally. **Usually the IRB recommends that compensation for younger children can take the form of a gift certificate to a toy store or children's bookstore or other item of particular interest to the age group being studied.**

It is also acceptable to compensate a parent or legal guardian for their time in the research when they sign the parental permission (informed consent) on behalf of their child.

INCENTIVES INVOLVING PRISONERS

For incentives involving prisoners, specific prison restrictions and requirements of the prison system must be considered.

OTHER FORMS OF COMPENSATION

Nominal gifts for study participation are allowed as long as the item does not display sponsor branding. For examples, when recruiting children, a small, age-appropriate gift or gift certificate may be provided to the child. Promotional items, course credit, or extra credit may also be given.

LOTTERIES, RAFFLES, AND DRAWINGS

There are various federal and state laws and statutes that apply to lotteries. The IRB discourages research-related drawings, raffles, and lotteries, as a form of compensation as they may trigger legal issues.

FINDER FEES

Payment (“finder’s fees”) paid to employees or investigators in exchange for referrals of prospective participants is not permitted at Downstate.

RECRUITMENT BONUSES TO INVESTIGATORS

Recruitment bonuses, additional payments from sponsors to an investigator or to Downstate based on rate or timing of enrollment is prohibited (e.g., additional payment beyond a fixed negotiated fee to accelerate recruitment). Such bonuses may place potential participants at risk of coercion or undue influence or cause an inequitable selection of participants.

ADMINISTRATIVE FEES AND COMPENSATION TO RESEARCH SITES

Administrative fees and compensation to research sites from a sponsor should not create any undue influence of investigators by creating inappropriate incentives for recruitment. Such funding should go to the site, not directly to an investigator. However, any payments made directly to investigators must be disclosed to the IRB for review on a case-by-case basis by the IRB and when applicable by the Financial Conflict of Interest Committee (FCOIC). The IRB or FCOIC may require written disclosures of any direct compensation to investigators within an informed consent document.

Sponsors may pay a consultant or external site to complete administrative or medical reviews of records or cases of participants enrolled into a study. In general, these fees could include fixed fees, startup costs, coordinator fees, fees for review the materials related to enrolled participants (e.g., medical chart review, demographic/diagnostic/clinical encounter case review), etc. However, such fees should be included in an agreement between the institutions and not directly with an employee or investigator who could possibly create undue influence in the recruitment or referral or a participant/patient or their data. It is recommended that any fees that are based only enrollment (rather than fixed fee) be disclosed in the research informed consent form to maintain transparency.

Contact Sponsored Programs for guidance on fees or compensation to another site.

IRB SUBMISSION

As applicable to the research, the following documents must be submitted to the Downstate IRB:

1. Description of screening, recruitment, and enrollment process and all incentives (gifts, awards. This may be included in the protocol, IRB application, or provided as a separate document.
2. Proposed advertisements (posters, fliers, brochures, printed ads, advertisements)
3. Proposed social media/Internet Ads (Facebook, Instagram, Twitter, social apps, etc.)
4. Recruitment e-mails, letters, or written scripts for telephone or verbal communications
5. Questionnaires or surveys that include information sheet or consent language
6. Informed consent document, pregnancy follow-up consent, assent documents, HIPAA Authorizations, SUNY RF Payment Consent, SUNY RF Payment Consent Waiver, and/or Short Forms
7. HIPAA Waivers and/or Waivers of Informed Consent
8. Subject Recruitment Authorization Forms and/or Medical Release Form

IRB REVIEW

The IRB will review all submitted materials to ensure it meets regulatory compliance and follows the above guidance. The IRB may consult with the consultants (listed on page 2-3) or others as needed for feedback before issuing final approval of the materials.

For example, the IRB may reach out to the Office of Communications & Marketing for review of social media ads to assure the proper corporate use of logo, font, color, as well as other graphic and style guidelines put forth by the Office of Communications & Marketing.

REFERENCES

- [FDA Guidance for informed consent.](#)
- [FDA Recruiting Study Subjects- Information Sheet.](#)
- [Borasky, D, Cooper, J, Fitzgerald, K. "Paying Subjects to Take Part in Research: A New Perspective on Coercion and Undue Influence." Clinical Researcher—March 2019 \(Volume 33, Issue 3\).](#)
- [Klitzman, R. "How IRBs view and make decisions about coercion and undue influence." J Med Ethics 20136 Apr; 39\(4\): 224-229.](#)
- [Largent EA, Lynch, HF. "Paying Research Participants: The Outsized Influence of 'Undue Influence' " IRB: 2017 Jul-Aug; 39\(4\):1-9.](#)
- [OHRP Guidance: FAQs](#)
- [OHRP Guidance: IRB Review of Clinical Trial Websites \(OHRP 2005\)](#)
- [U.S. Department of Health and Human Services \(HHS\) Regulations for Protection of Research Participants under 45 CFR 46.116 \(July 19, 2018\)](#)
- [U.S. Food and Drug Administration \(FDA\) regulations under 21 CFR 11, 50, 56, 312, 812, and 814](#)
- [University of South Alabama IRB SOP 1203: Compensation/Incentives for Research Participation](#)

AUTHORS

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With feedback from:

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With Gratitude for sharing advertisement example
 Ozgul Muneyyirci-Delale, M.D.

REVIEW AND APPROVAL HISTORY

Original Issue Date: 12/2/2016

Supersedes: 02/04/2021

Revised Date: 05/09/2021

Effective Date: 05/09/2021

Date Reviewed & Approved	Revision Required		Responsible Staff Name and Title	
	Yes	No		
12/2/2016		X	Kevin L. Nellis, MS Executive Director, Human Research Protections and Quality Improvement.	
03/02/2017	X		Kevin L. Nellis, MS Executive Director, Human Research Protections and Quality Improvement.	
02/04/2021	X		Kevin L. Nellis, MS Executive Director, Human Research Protections and Quality Improvement.	

			Clinton D. Brown, MD, FASN, FAHA, FNLA, IRB Chair	
05/10/2021	X		<p>Alexandra Bliss, CHC, CPHIT, CPEHR - Director of Compliance</p> <p>Clinton D. Brown, MD, FASN, FAHA, FNLA, IRB Chair</p> <p>Stanley Friedman, MD IRB Vice-Chair</p> <p>Shoshana Milstein, CHC, CHP, RHIA, CCS - Vice President, Compliance and Audit Services</p> <p>Kevin L. Nellis, MS Executive Director, Human Research Protections and Quality Improvement.</p> <p>Dawn S. Walker, MPA, VP of Communications & Marketing</p>	Updated guidance to provide more details on how to check patient directory, updated information on monetary compensation, and provided more details on ads, including social media.